

107TH CONGRESS
1ST SESSION

S. 889

To protect consumers in managed care plans and in other health coverage.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2001

Mr. FRIST (for himself, Mr. BREAU, and Mr. JEFFORDS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To protect consumers in managed care plans and in other health coverage.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Bipartisan Patients’ Bill of Rights Act of 2001”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—PATIENTS’ BILL OF RIGHTS

Subtitle A—Right to Advice and Care

Sec. 101. Access to emergency medical care.

Sec. 102. Offering of choice of coverage options.

- Sec. 103. Patient access to obstetric and gynecological care.
- Sec. 104. Access to pediatric care.
- Sec. 105. Timely access to specialists.
- Sec. 106. Continuity of care.
- Sec. 107. Protection of patient-provider communications.
- Sec. 108. Patient's right to prescription drugs.
- Sec. 109. Coverage for individuals participating in approved clinical trials.
- Sec. 110. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.
- Sec. 111. Prohibition of discrimination against providers based on licensure.
- Sec. 112. Generally applicable provision.

Subtitle B—Right to Information About Plans and Providers

- Sec. 121. Health plan information.
- Sec. 122. Information about providers.
- Sec. 123. Study on the effect of physician compensation methods.

Subtitle C—Right to Hold Health Plans Accountable

- Sec. 131. Amendments to Employee Retirement Income Security Act of 1974.
- Sec. 132. Enforcement.

Subtitle D—Remedies

- Sec. 141. Availability of court remedies.
- Sec. 142. Limitation on certain class action litigation.
- Sec. 143. Authority to impose civil penalties for failure to provide a plan benefit not eligible for medical review.

Subtitle E—State Flexibility

- Sec. 151. Preemption; State flexibility; construction.
- Sec. 152. Coverage of limited scope dental plans.

Subtitle F—Miscellaneous Provisions

- Sec. 161. Definitions.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to certain health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.
- Sec. 203. Limitation on authority of the Secretary of Health and Human services with respect to non-Federal governmental plans.
- Sec. 204. Cooperation between Federal and State authorities.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 302. Cooperation between Federal and State authorities.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Sec. 401. Application to group health plans under the Internal Revenue Code of 1986.

Sec. 402. Conforming enforcement for women's health and cancer rights.

TITLE V—EFFECTIVE DATE; SEVERABILITY

Sec. 501. Effective date and related rules.

Sec. 502. Severability.

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

SEC. 101. ACCESS TO EMERGENCY MEDICAL CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—If a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage for any benefits consisting of emergency medical care, except for items or services specifically excluded from coverage, the plan or issuer shall, without regard to prior authorization or provider participation—

(1) provide coverage for emergency medical screening examinations to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary; and

(2) provide coverage for additional emergency medical care to stabilize an emergency medical condition following an emergency medical screening examination (if determined necessary), pursuant to the

1 definition of stabilize under section 1867(e)(3) of the
2 Social Security Act (42 U.S.C. 1395dd(e)(3)).

3 (b) COVERAGE OF EMERGENCY AMBULANCE SERV-
4 ICES.—If a group health plan, and a health insurance
5 issuer that offers health insurance coverage, provides cov-
6 erage for any benefits consisting of emergency ambulance
7 services, except for items or services specifically excluded
8 from coverage, the plan or issuer shall, without regard to
9 prior authorization or provider participation, provide cov-
10 erage for emergency ambulance services to the extent that
11 a prudent layperson, who possesses an average knowledge
12 of health and medicine, would determine such emergency
13 ambulance services to be necessary.

14 (c) CARE AFTER STABILIZATION.—

15 (1) IN GENERAL.—In the case of medically nec-
16 essary and appropriate items or services related to
17 the emergency medical condition that may be pro-
18 vided to a participant, beneficiary, or enrollee by a
19 nonparticipating provider after the participant, bene-
20 ficiary, or enrollee is stabilized, the nonparticipating
21 provider shall contact the plan or issuer as soon as
22 practicable, but not later than 1 hour after stabiliza-
23 tion occurs, with respect to whether—

24 (A) the provision of items or services is ap-
25 proved;

1 (B) the participant, beneficiary, or enrollee
2 will be transferred; or

3 (C) other arrangements will be made con-
4 cerning the care and treatment of the partici-
5 pant, beneficiary, or enrollee.

6 (2) FAILURE TO RESPOND AND MAKE AR-
7 RANGEMENTS.—If a group health plan, and a health
8 insurance issuer that offers health insurance cov-
9 erage, fails to respond and make arrangements with-
10 in 1 hour of being contacted in accordance with
11 paragraph (1), then the plan or issuer shall be re-
12 sponsible for the cost of any additional items or
13 services provided by the nonparticipating provider
14 if—

15 (A) coverage for items or services of the
16 type furnished by the nonparticipating provider
17 is available under the plan or coverage;

18 (B) the items or services are medically nec-
19 essary and appropriate and related to the emer-
20 gency medical condition involved; and

21 (C) the timely provision of the items or
22 services is medically necessary and appropriate.

23 (3) RULE OF CONSTRUCTION.—Nothing in this
24 subsection shall be construed to apply to a group
25 health plan, and a health insurance issuer that of-

1 fers health insurance coverage, that does not require
 2 prior authorization for items or services provided to
 3 a participant, beneficiary, or enrollee after the par-
 4 ticipant, beneficiary, or enrollee is stabilized.

5 (d) REIMBURSEMENT TO A NONPARTICIPATING PRO-
 6 VIDER.—The responsibility of a group health plan, and a
 7 health insurance issuer that offers health insurance cov-
 8 erage, to provide reimbursement to a nonparticipating pro-
 9 vider under this section shall cease accruing upon the ear-
 10 lier of—

11 (1) the transfer or discharge of the participant,
 12 beneficiary, or enrollee; or

13 (2) the completion of other arrangements made
 14 by the plan or issuer and the nonparticipating pro-
 15 vider.

16 (e) RESPONSIBILITY OF PARTICIPANT.—The cov-
 17 erage required under subsections (a), (b), and (c) shall
 18 be provided by a group health plan, and a health insurance
 19 issuer that offers health insurance coverage, in a manner
 20 so that, if the services referred to in such subsections are
 21 provided to a participant, beneficiary, or enrollee by a non-
 22 participating provider with or without prior authorization,
 23 the participant, beneficiary, or enrollee is not liable for
 24 amounts that exceed the amounts of liability that would

1 be incurred if the services were provided by a participating
 2 health care provider with prior authorization.

3 (f) RULE OF CONSTRUCTION.—Nothing in this sec-
 4 tion shall be construed to prohibit a group health plan or
 5 health insurance issuer from negotiating reimbursement
 6 rates with a nonparticipating provider for items or services
 7 provided under this section.

8 (g) DEFINITIONS.—In this section:

9 (1) EMERGENCY AMBULANCE SERVICES.—The
 10 term “emergency ambulance services” means, with
 11 respect to a participant, beneficiary, or enrollee
 12 under a group health plan, or a health insurance
 13 issuer that offers health insurance coverage, ambu-
 14 lance services furnished to transport an individual
 15 who has an emergency medical condition to a treat-
 16 ing facility for receipt of emergency medical care
 17 if—

18 (A) the emergency services are covered
 19 under the group health plan or health insurance
 20 coverage involved; and

21 (B) a prudent layperson who possesses an
 22 average knowledge of health and medicine could
 23 reasonably expect the absence of such emer-
 24 gency transport to result in placing the health
 25 of the participant, beneficiary, or enrollee (or,

1 with respect to a pregnant woman, the health
2 of the woman or her unborn child) in serious
3 jeopardy, serious impairment to bodily func-
4 tions, or serious dysfunction of any bodily organ
5 or part.

6 (2) EMERGENCY MEDICAL CARE.—The term
7 “emergency medical care” means, with respect to a
8 participant, beneficiary, or enrollee under a group
9 health plan, or a health insurance issuer that offers
10 health insurance coverage, covered inpatient and
11 outpatient items or services that—

12 (A) are furnished by any provider, includ-
13 ing a nonparticipating provider, that is qualified
14 to furnish such items or services; and

15 (B) are needed to evaluate or stabilize (as
16 such term is defined in section 1867(e)(3) of
17 the Social Security Act (42 U.S.C.
18 1395dd(e)(3)) an emergency medical condition.

19 (3) EMERGENCY MEDICAL CONDITION.—The
20 term “emergency medical condition” means a med-
21 ical condition manifesting itself by acute symptoms
22 of sufficient severity (including severe pain) such
23 that a prudent layperson, who possesses an average
24 knowledge of health and medicine, could reasonably
25 expect the absence of immediate medical attention to

1 result in placing the health of the participant, bene-
 2 ficiary, or enrollee (or, with respect to a pregnant
 3 woman, the health of the woman or her unborn
 4 child) in serious jeopardy, serious impairment to
 5 bodily functions, or serious dysfunction of any bodily
 6 organ or part.

7 **SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS.**

8 (a) REQUIREMENT.—If a group health plan provides
 9 coverage for benefits only through a defined set of partici-
 10 pating health care professionals, the plan shall offer the
 11 participant the option to purchase point-of-service cov-
 12 erage (as defined in subsection (b)) for all such benefits
 13 for which coverage is otherwise so limited. Such option
 14 shall be made available to the participant at the time of
 15 enrollment under the plan and at such other times as the
 16 plan offers the participant a choice of coverage options.

17 (b) POINT-OF-SERVICE COVERAGE DEFINED.—In
 18 this section, the term “point-of-service coverage” means,
 19 with respect to benefits covered under a group health plan
 20 coverage of such benefits when provided by a nonpartici-
 21 pating health care professional.

22 (c) SMALL EMPLOYER EXEMPTION.—

23 (1) IN GENERAL.—This section shall not apply
 24 to any group health plan with respect to a small em-
 25 ployer.

1 (2) SMALL EMPLOYER.—For purposes of para-
 2 graph (1), the term “small employer” means, in con-
 3 nection with a group health plan with respect to a
 4 calendar year and a plan year, an employer who em-
 5 ployed an average of at least 2 but not more than
 6 25 employees on business days during the preceding
 7 calendar year and who employs at least 2 employees
 8 on the first day of the plan year. For purposes of
 9 this paragraph, the provisions of subparagraph (C)
 10 of section 712(c)(1) shall apply in determining em-
 11 ployer size.

12 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
 13 tion shall be construed—

14 (1) as requiring coverage for benefits for a par-
 15 ticular type of health care professional;

16 (2) as preventing a group health plan from im-
 17 posing higher premiums or cost-sharing on a partici-
 18 pant for the exercise of a point-of-service coverage
 19 option; or

20 (3) to require that a group health plan include
 21 coverage of health care professionals that the plan
 22 excludes because of fraud, quality of care, or other
 23 similar reasons with respect to such professionals.

24 (e) SPECIAL POINT OF SERVICE PROTECTION FOR
 25 INDIVIDUALS IN DENTAL PLANS.—For purposes of apply-

1 ing the requirements of this section under sections 2707
 2 and 2753 of the Public Health Service Act and section
 3 714 of the Employee Retirement Income Security Act of
 4 1974, section 2791(c)(2)(A) of the Public Health Service
 5 Act and section 733(c)(2)(A) of the Employee Retirement
 6 Income Security Act of 1974, only relating to limited
 7 scope dental benefits, shall be deemed not to apply.

8 **SEC. 103. PATIENT ACCESS TO OBSTETRIC AND GYNECO-**
 9 **LOGICAL CARE.**

10 (a) GENERAL RIGHTS.—

11 (1) DIRECT ACCESS.—A group health plan, and
 12 a health insurance issuer that offers health insur-
 13 ance coverage, described in subsection (b) may not
 14 require authorization or referral by the primary care
 15 provider described in subsection (b)(2) in the case of
 16 a female participant, beneficiary, or enrollee who
 17 seeks coverage for obstetrical or gynecological care
 18 provided by a participating physician who specializes
 19 in obstetrics or gynecology.

20 (2) OBSTETRICAL AND GYNECOLOGICAL
 21 CARE.—A group health plan, and a health insurance
 22 issuer that offers health insurance coverage, de-
 23 scribed in subsection (b) shall treat the provision of
 24 obstetrical and gynecological care, and the ordering
 25 of related obstetrical and gynecological items and

1 services, pursuant to the direct access described
2 under paragraph (1), by a participating health care
3 professional who specializes in obstetrics or gyne-
4 cology as the authorization of the primary care pro-
5 vider.

6 (b) APPLICATION OF SECTION.—A group health plan,
7 and a health insurance issuer that offers health insurance
8 coverage, described in this subsection is a plan or issuer,
9 that—

10 (1) provides coverage for obstetric or
11 gynecologic care; and

12 (2) requires the designation by a participant,
13 beneficiary, or enrollee of a participating primary
14 care provider other than a physician who specializes
15 in obstetrics or gynecology.

16 (c) RULES OF CONSTRUCTION.—Nothing in this sec-
17 tion shall be construed—

18 (1) to require that a group health plan or a
19 health insurance issuer approve or provide coverage
20 for—

21 (A) any items or services that are not cov-
22 ered under the terms and conditions of the plan
23 or coverage;

24 (B) any items or services that are not
25 medically necessary and appropriate; or

1 (C) any items or services that are pro-
2 vided, ordered, or otherwise authorized under
3 subsection (a)(2) by a physician unless such
4 items or services are related to obstetric or
5 gynecologic care;

6 (2) to preclude a group health plan or health
7 insurance issuer from requiring that the physician
8 described in subsection (a) notify the designated pri-
9 mary care professional or case manager of treatment
10 decisions in accordance with a process implemented
11 by the plan or issuer, except that the plan or issuer
12 shall not impose such a notification requirement on
13 the participant, beneficiary, or enrollee involved in
14 the treatment decision;

15 (3) to preclude a group health plan or health
16 insurance issuer from requiring authorization, in-
17 cluding prior authorization, for certain items and
18 services from the physician described in subsection
19 (a) who specializes in obstetrics and gynecology if
20 the designated primary care provider of the partici-
21 pant, beneficiary, or enrollee would otherwise be re-
22 quired to obtain authorization for such items or
23 services;

24 (4) to require that the participant, beneficiary,
25 or enrollee described in subsection (a)(1) obtain au-

1 thorization or a referral from a primary care pro-
 2 vider in order to obtain obstetrical or gynecological
 3 care from a health care professional other than a
 4 physician if the provision of obstetrical or gynecolo-
 5 gical care by such professional is permitted by the
 6 group health plan or health insurance coverage and
 7 consistent with State licensure, credentialing, and
 8 scope of practice laws and regulations; or

9 (5) to preclude the participant, beneficiary, or
 10 enrollee described in subsection (a)(1) from desig-
 11 nating a health care professional other than a physi-
 12 cian as a primary care provider if such designation
 13 is permitted by the group health plan or health in-
 14 surance issuer and the treatment by such profes-
 15 sional is consistent with State licensure,
 16 credentialing, and scope of practice laws and regula-
 17 tions.

18 **SEC. 104. ACCESS TO PEDIATRIC CARE.**

19 (a) PEDIATRIC CARE.—If a group health plan, and
 20 a health insurance issuer that offers health insurance cov-
 21 erage, requires or provides for a participant, beneficiary,
 22 or enrollee to designate a participating primary care pro-
 23 vider for a child of such participant, beneficiary, or en-
 24 rollee, the plan or issuer shall permit the participant, ben-
 25 eficiary, or enrollee to designate a physician who special-

1 izes in pediatrics as the child's primary care provider if
 2 such provider participates in the network of the plan or
 3 issuer.

4 (b) RULES OF CONSTRUCTION.—With respect to the
 5 child of a participant, beneficiary, or enrollee, nothing in
 6 subsection (a) shall be construed to—

7 (1) require that the participant, beneficiary, or
 8 enrollee obtain prior authorization or a referral from
 9 a primary care provider in order to obtain pediatric
 10 care from a health care professional other than a
 11 physician if the provision of pediatric care by such
 12 professional is permitted by the plan or issuer and
 13 consistent with State licensure, credentialing, and
 14 scope of practice laws and regulations; or

15 (2) preclude the participant, beneficiary, or en-
 16 rollee from designating a health care professional
 17 other than a physician as a primary care provider
 18 for the child if such designation is permitted by the
 19 plan or issuer and the treatment by such profes-
 20 sional is consistent with State licensure,
 21 credentialing, and scope of practice laws.

22 **SEC. 105. TIMELY ACCESS TO SPECIALISTS.**

23 (a) TIMELY ACCESS.—

24 (1) REQUIREMENT OF COVERAGE.—

1 (A) IN GENERAL.—A group health plan,
 2 and a health insurance issuer that offers health
 3 insurance coverage, shall ensure that partici-
 4 pants, beneficiaries, and enrollees receive timely
 5 coverage for access to appropriate medical spe-
 6 cialists when such specialty care is a covered
 7 benefit under the plan or coverage.

8 (B) APPROPRIATE MEDICAL SPECIALIST
 9 DEFINED.—In this subsection, the term “appro-
 10 priate medical specialist” means a physician
 11 (including an alleopathic or osteopathic physi-
 12 cian) or health care professional who is appro-
 13 priately credentialed or licensed in 1 or more
 14 States and who typically treats the diagnosis or
 15 condition of the participant, beneficiary, or en-
 16 rollee.

17 (2) RULE OF CONSTRUCTION.—Nothing in
 18 paragraph (1) shall be construed—

19 (A) to require the coverage under a group
 20 health plan, or health insurance coverage, of
 21 benefits or services;

22 (B) to prohibit a plan or health insurance
 23 issuer from including providers in the network
 24 only to the extent necessary to meet the needs

of the plan's or issuer's participants, beneficiaries, or enrollees;

(C) to prohibit a plan or issuer from establishing measures designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

(D) to override any State licensure or scope-of-practice law.

(3) ACCESS TO CERTAIN PROVIDERS.—

(A) PARTICIPATING PROVIDERS.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from requiring that a participant, beneficiary, or enrollee obtain specialty care from a participating specialist.

(B) NONPARTICIPATING PROVIDERS.—

(i) IN GENERAL.—With respect to specialty care under this section, if a group health plan, or a health insurance issuer that offers health insurance coverage, determines that a participating specialist is not available to provide such care to the participant, beneficiary, or enrollee, the

1 plan or issuer shall provide for coverage of
 2 such care by a nonparticipating specialist.

3 (ii) TREATMENT OF NONPARTICI-
 4 PATING PROVIDERS.—If a group health
 5 plan, or a health insurance issuer that of-
 6 fers health insurance coverage, refers a
 7 participant, beneficiary, or enrollee to a
 8 nonparticipating specialist pursuant to
 9 clause (i), such specialty care shall be pro-
 10 vided at no additional cost to the partici-
 11 pant, beneficiary, or enrollee beyond what
 12 the participant, beneficiary, or enrollee
 13 would otherwise pay for such specialty care
 14 if provided by a participating specialist.

15 (b) REFERRALS.—

16 (1) AUTHORIZATION.—Nothing in this section
 17 shall be construed to prohibit a group health plan,
 18 or a health insurance issuer that offers health insur-
 19 ance coverage, from requiring an authorization in
 20 order to obtain coverage for specialty services so
 21 long as such authorization is for an appropriate du-
 22 ration or number of referrals.

23 (2) REFERRALS FOR ONGOING SPECIAL CONDI-
 24 TIONS.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall permit a participant, beneficiary, or enrollee who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the terms of a treatment plan referred to in subsection (c) with respect to the condition.

(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term “ongoing special condition” means a condition or disease that—

(i) is life-threatening, degenerative, or disabling; and

(ii) requires specialized medical care over a prolonged period of time.

(c) TREATMENT PLANS.—

(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance

1 coverage, from requiring that specialty care be pro-
2 vided pursuant to a treatment plan so long as the
3 treatment plan is—

4 (A) developed by the specialist, in consulta-
5 tion with the case manager or primary care pro-
6 vider, and the participant, beneficiary, or en-
7 rollee; and

8 (B) if the plan or issuer requires such ap-
9 proval, approved in a timely manner by the plan
10 or issuer consistent with the applicable quality
11 assurance and utilization review standards of
12 the plan or issuer.

13 (2) NOTIFICATION.—Nothing in paragraph (1)
14 shall be construed as prohibiting a plan or issuer
15 from requiring the specialist to provide the plan or
16 issuer with regular updates on the specialty care
17 provided, as well as all other necessary medical in-
18 formation.

19 (d) SPECIALIST DEFINED.—For purposes of this sec-
20 tion, the term “specialist” means, with respect to the med-
21 ical condition of the participant, beneficiary, or enrollee,
22 a health care professional, facility, or center (such as a
23 center of excellence) that has adequate expertise (includ-
24 ing age-appropriate expertise) through appropriate train-
25 ing and experience.

1 **SEC. 106. CONTINUITY OF CARE.**

2 (a) **TERMINATION OF PROVIDER.**—If a contract be-
3 tween a group health plan, and a health insurance issuer
4 that offers health insurance coverage, and a treating
5 health care provider is terminated (as defined in para-
6 graph (e)(4)), or benefits or coverage provided by a health
7 care provider are terminated because of a change in the
8 terms of provider participation in such plan or coverage,
9 and an individual who is a participant, beneficiary or en-
10 rollee under such plan or coverage is undergoing an active
11 course of treatment for a serious and complex condition,
12 institutional care, pregnancy, or terminal illness from the
13 provider at the time the plan or issuer receives or provides
14 notice of such termination, the plan or issuer shall—

15 (1) notify the individual, or arrange to have the
16 individual notified pursuant to subsection (d)(2), on
17 a timely basis of such termination;

18 (2) provide the individual with an opportunity
19 to notify the plan or issuer of the individual's need
20 for transitional care; and

21 (3) subject to subsection (c), permit the indi-
22 vidual to elect to continue to be covered with respect
23 to the active course of treatment with the provider's
24 consent during a transitional period (as provided for
25 under subsection (b)).

26 (b) **TRANSITIONAL PERIOD.**—

1 (1) SERIOUS AND COMPLEX CONDITIONS.—The
2 transitional period under this section with respect to
3 a serious and complex condition shall extend for up
4 to 90 days from the date of the notice described in
5 subsection (a)(1) of the provider’s termination.

6 (2) INSTITUTIONAL OR INPATIENT CARE.—

7 (A) IN GENERAL.—The transitional period
8 under this section for institutional or non-elec-
9 tive inpatient care from a provider shall extend
10 until the earlier of—

11 (i) the expiration of the 90-day period
12 beginning on the date on which the notice
13 described in subsection (a)(1) of the pro-
14 vider’s termination is provided; or

15 (ii) the date of discharge of the indi-
16 vidual from such care or the termination of
17 the period of institutionalization.

18 (B) SCHEDULED CARE.—The 90 day limi-
19 tation described in subparagraph (A)(i) shall in-
20 clude post-surgical follow-up care relating to
21 non-elective surgery that has been scheduled be-
22 fore the date of the notice of the termination of
23 the provider under subsection (a)(1).

24 (3) PREGNANCY.—If—

1 (A) a participant, beneficiary, or enrollee
 2 has entered the second trimester of pregnancy
 3 at the time of a provider's termination of par-
 4 ticipation; and

5 (B) the provider was treating the preg-
 6 nancy before the date of the termination;
 7 the transitional period under this subsection with re-
 8 spect to provider's treatment of the pregnancy shall
 9 extend through the provision of post-partum care di-
 10 rectly related to the delivery.

11 (4) TERMINAL ILLNESS.—If—

12 (A) a participant, beneficiary, or enrollee
 13 was determined to be terminally ill (as deter-
 14 mined under section 1861(dd)(3)(A) of the So-
 15 cial Security Act) at the time of a provider's
 16 termination of participation; and

17 (B) the provider was treating the terminal
 18 illness before the date of termination;
 19 the transitional period under this subsection shall
 20 extend for the remainder of the individual's life for
 21 care that is directly related to the treatment of the
 22 terminal illness.

23 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
 24 group health plan, and a health insurance issuer that of-
 25 fers health insurance coverage, may condition coverage of

1 continued treatment by a provider under this section upon
2 the provider agreeing to the following terms and condi-
3 tions:

4 (1) The treating health care provider agrees to
5 accept reimbursement from the plan or issuer and
6 individual involved (with respect to cost-sharing) at
7 the rates applicable prior to the start of the transi-
8 tional period as payment in full (or at the rates ap-
9 plicable under the replacement plan after the date of
10 the termination of the contract with the plan or
11 issuer) and not to impose cost-sharing with respect
12 to the individual in an amount that would exceed the
13 cost-sharing that could have been imposed if the
14 contract referred to in this section had not been ter-
15 minated.

16 (2) The treating health care provider agrees to
17 adhere to the quality assurance standards of the
18 plan or issuer responsible for payment under para-
19 graph (1) and to provide to such plan or issuer nec-
20 essary medical information related to the care pro-
21 vided.

22 (3) The treating health care provider agrees
23 otherwise to adhere to such plan's or issuer's policies
24 and procedures, including procedures regarding re-
25 ferrals and obtaining prior authorization and pro-

1 viding services pursuant to a treatment plan (if any)
 2 approved by the plan or issuer.

3 (d) RULES OF CONSTRUCTION.—Nothing in this sec-
 4 tion shall be construed—

5 (1) to require the coverage of benefits which
 6 would not have been covered if the provider involved
 7 remained a participating provider; or

8 (2) with respect to the termination of a con-
 9 tract under subsection (a) to prevent a group health
 10 plan or health insurance issuer from requiring that
 11 the health care provider—

12 (A) notify participants, beneficiaries, or en-
 13 rollees of their rights under this section; or

14 (B) provide the plan or issuer with the
 15 name of each participant, beneficiary, or en-
 16 rollee who the provider believes is eligible for
 17 transitional care under this section.

18 (e) DEFINITIONS.—In this section:

19 (1) CONTRACT.—The term “contract between a
 20 group health plan, and a health insurance issuer
 21 that offers health insurance coverage, and a treating
 22 health care provider” shall include a contract be-
 23 tween such a plan or issuer and an organized net-
 24 work of providers.

1 (2) HEALTH CARE PROVIDER.—The term
2 “health care provider” or “provider” means—

3 (A) any individual who is engaged in the
4 delivery of health care services in a State and
5 who is required by State law or regulation to be
6 licensed or certified by the State to engage in
7 the delivery of such services in the State; and

8 (B) any entity that is engaged in the deliv-
9 ery of health care services in a State and that,
10 if it is required by State law or regulation to be
11 licensed or certified by the State to engage in
12 the delivery of such services in the State, is so
13 licensed.

14 (3) SERIOUS AND COMPLEX CONDITION.—The
15 term “serious and complex condition” means, with
16 respect to a participant, beneficiary, or enrollee
17 under the plan or coverage, a condition that is medi-
18 cally determinable and—

19 (A) in the case of an acute illness, is a
20 condition serious enough to require specialized
21 medical treatment to avoid the reasonable possi-
22 bility of death or permanent harm; or

23 (B) in the case of a chronic illness or con-
24 dition, is an illness or condition that—

25 (i) is complex and difficult to manage;

1 (ii) is disabling or life-threatening;

2 and

3 (iii) requires—

4 (I) frequent monitoring over a
5 prolonged period of time and requires
6 substantial on-going specialized med-
7 ical care; or

8 (II) frequent ongoing specialized
9 medical care across a variety of do-
10 mains of care.

11 (4) TERMINATED.—The term “terminated” in-
12 cludes, with respect to a contract (as defined in
13 paragraph (1)), the expiration or nonrenewal of the
14 contract by the group health plan or health insur-
15 ance issuer, but does not include a termination of
16 the contract by the plan or issuer for failure to meet
17 applicable quality standards or for fraud.

18 **SEC. 107. PROTECTION OF PATIENT-PROVIDER COMMU-**
19 **NICATIONS.**

20 (a) IN GENERAL.—Subject to subsection (b), a group
21 health plan, and a health insurance issuer that offers
22 health insurance coverage, (in relation to a participant,
23 beneficiary, or enrollee) shall not prohibit or otherwise re-
24 strict a health care professional from advising such a par-
25 ticipant, beneficiary, or enrollee who is a patient of the

1 professional about the health status of the participant,
 2 beneficiary, or enrollee or medical care or treatment for
 3 the condition or disease of the participant, beneficiary, or
 4 enrollee, regardless of whether coverage for such care or
 5 treatment are provided under the contract, if the profes-
 6 sional is acting within the lawful scope of practice.

7 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
 8 tion shall be construed as requiring a group health plan,
 9 or a health insurance issuer that offers health insurance
 10 coverage, to provide specific benefits under the terms of
 11 such plan or coverage.

12 **SEC. 108. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.**

13 (a) IN GENERAL.—To the extent that a group health
 14 plan, and a health insurance issuer that offers health in-
 15 surance coverage, provides coverage for benefits with re-
 16 spect to prescription drugs, and limits such coverage to
 17 drugs included in a formulary, the plan or issuer shall—

18 (1) ensure the participation of physicians and
 19 pharmacists in developing and reviewing such for-
 20 mulary; and

21 (2) in accordance with the applicable quality as-
 22 surance and utilization review standards of the plan
 23 or issuer, provide for exceptions from the formulary
 24 limitation when a non-formulary alternative is medi-
 25 cally necessary and appropriate.

1 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
 2 tion shall be construed to prohibit a group health plan,
 3 or a health insurance issuer that offers health insurance
 4 coverage, from excluding coverage for a specific drug or
 5 class of drugs if such drugs or class of drugs is expressly
 6 excluded under the terms and conditions of the plan or
 7 coverage.

8 **SEC. 109. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 9 **APPROVED CLINICAL TRIALS.**

10 (a) COVERAGE.—

11 (1) IN GENERAL.—If a group health plan, and
 12 a health insurance issuer that offers health insur-
 13 ance coverage, provides coverage to a qualified indi-
 14 vidual (as defined in subsection (b)), the plan or
 15 issuer—

16 (A) may not deny the individual participa-
 17 tion in the clinical trial referred to in subsection
 18 (b)(2);

19 (B) subject to subsections (b), (c), and (d)
 20 may not deny (or limit or impose additional
 21 conditions on) the coverage of routine patient
 22 costs for items and services furnished in con-
 23 nection with participation in the trial; and

1 (C) may not discriminate against the indi-
2 vidual on the basis of the participant's, bene-
3 ficiaries, or enrollee's participation in such trial.

4 (2) EXCLUSION OF CERTAIN COSTS.—For pur-
5 poses of paragraph (1)(B), routine patient costs do
6 not include the cost of the tests or measurements
7 conducted primarily for the purpose of the clinical
8 trial involved.

9 (3) USE OF IN-NETWORK PROVIDERS.—If one
10 or more participating providers is participating in a
11 clinical trial, nothing in paragraph (1) shall be con-
12 strued as preventing a plan or issuer from requiring
13 that a qualified individual participate in the trial
14 through such a participating provider if the provider
15 will accept the individual as a participant in the
16 trial.

17 (b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
18 poses of subsection (a), the term “qualified individual”
19 means an individual who is a participant or beneficiary
20 in a group health plan or an enrollee in health insurance
21 coverage and who meets the following conditions:

22 (1)(A) The individual has a life-threatening or
23 serious illness for which no standard treatment is ef-
24 fective.

1 (B) The individual is eligible to participate in
 2 an approved clinical trial according to the trial pro-
 3 tocol with respect to treatment of such illness.

4 (C) The individual's participation in the trial
 5 offers meaningful potential for significant clinical
 6 benefit for the individual.

7 (2) Either—

8 (A) the referring physician is a partici-
 9 pating health care professional and has con-
 10 cluded that the individual's participation in
 11 such trial would be appropriate based upon the
 12 individual meeting the conditions described in
 13 paragraph (1); or

14 (B) the participant, beneficiary, or enrollee
 15 provides medical and scientific information es-
 16 tablishing that the individual's participation in
 17 such trial would be appropriate based upon the
 18 individual meeting the conditions described in
 19 paragraph (1).

20 (c) PAYMENT.—

21 (1) IN GENERAL.—Under this section a group
 22 health plan, and a health insurance issuer that of-
 23 fers health insurance coverage, shall provide for pay-
 24 ment for routine patient costs described in sub-
 25 section (a)(2) but is not required to pay for costs of

1 items and services that are reasonably expected to be
 2 paid for by the sponsors of an approved clinical trial.

3 (2) STANDARDS FOR DETERMINING ROUTINE
 4 PATIENT COSTS ASSOCIATED WITH CLINICAL TRIAL
 5 PARTICIPATION.—

6 (A) IN GENERAL.—The Secretary shall, in
 7 accordance with this paragraph, establish
 8 standards relating to the coverage of routine
 9 patient costs for individuals participating in
 10 clinical trials that group health plans and
 11 health insurance issuers must meet under this
 12 section.

13 (B) FACTORS.—In establishing routine pa-
 14 tient cost standards under subparagraph (A),
 15 the Secretary shall consult with interested par-
 16 ties and take into account —

17 (i) quality of patient care;

18 (ii) routine patient care costs versus
 19 costs associated with the conduct of clinical
 20 trials, including unanticipated patient care
 21 costs as a result of participation in clinical
 22 trials; and

23 (iii) previous and on-going studies re-
 24 lating to patient care costs associated with
 25 participation in clinical trials.

1 (C) APPOINTMENT AND MEETINGS OF NE-
2 GOTIATED RULEMAKING COMMITTEE.—

3 (i) PUBLICATION OF NOTICE.—Not
4 later than November 15, 2002, the Sec-
5 retary shall publish notice of the establish-
6 ment of a negotiated rulemaking com-
7 mittee, as provided for under section
8 564(a) of title 5, United States Code, to
9 develop the standards described in sub-
10 paragraph (A), which shall include—

11 (I) the proposed scope of the
12 committee;

13 (II) the interests that may be im-
14 pacted by the standards;

15 (III) a list of the proposed mem-
16 bership of the committee;

17 (IV) the proposed meeting sched-
18 ule of the committee;

19 (V) a solicitation for public com-
20 ment on the committee; and

21 (VI) the procedures under which
22 an individual may apply for member-
23 ship on the committee.

24 (ii) COMMENT PERIOD.—Notwith-
25 standing section 564(c) of title 5, United

1 States Code, the Secretary shall provide
2 for a period, beginning on the date on
3 which the notice is published under clause
4 (i) and ending on November 30, 2002, for
5 the submission of public comments on the
6 committee under this subparagraph.

7 (iii) APPOINTMENT OF COMMITTEE.—
8 Not later than December 30, 2001, the
9 Secretary shall appoint the members of the
10 negotiated rulemaking committee under
11 this subparagraph.

12 (iv) FACILITATOR.—Not later than
13 January 10, 2003, the negotiated rule-
14 making committee shall nominate a
15 facilitator under section 566(c) of title 5,
16 United States Code, to carry out the activi-
17 ties described in subsection (d) of such sec-
18 tion.

19 (v) MEETINGS.—During the period
20 beginning on the date on which the
21 facilitator is nominated under clause (iv)
22 and ending on March 30, 2003, the nego-
23 tiated rulemaking committee shall meet to
24 develop the standards described in sub-
25 paragraph (A).

1 (D) PRELIMINARY COMMITTEE REPORT.—

2 (i) IN GENERAL.—The negotiated
3 rulemaking committee appointed under
4 subparagraph (C) shall report to the Sec-
5 retary, by not later than March 30, 2003,
6 regarding the committee's progress on
7 achieving a consensus with regard to the
8 rulemaking proceedings and whether such
9 consensus is likely to occur before the tar-
10 get date described in subsection (F).

11 (ii) TERMINATION OF PROCESS AND
12 PUBLICATION OF RULE BY SECRETARY.—If
13 the committee reports under clause (i) that
14 the committee has failed to make signifi-
15 cant progress towards such consensus or is
16 unlikely to reach such consensus by the
17 target date described in subsection (F), the
18 Secretary shall terminate such process and
19 provide for the publication in the Federal
20 Register, by not later than June 30, 2003,
21 of a rule under this paragraph through
22 such other methods as the Secretary may
23 provide.

24 (E) FINAL COMMITTEE REPORT AND PUB-
25 LICATION OF RULE BY SECRETARY.—

1 (i) IN GENERAL.—If the rulemaking
 2 committee is not terminated under sub-
 3 paragraph (D)(ii), the committee shall sub-
 4 mit to the Secretary, by not later than
 5 May 30, 2003, a report containing a pro-
 6 posed rule.

7 (ii) PUBLICATION OF RULE.—If the
 8 Secretary receives a report under clause
 9 (i), the Secretary shall provide for the pub-
 10 lication in the Federal Register, by not
 11 later than June 30, 2003, of the proposed
 12 rule.

13 (F) TARGET DATE FOR PUBLICATION OF
 14 RULE.—As part of the notice under subpara-
 15 graph (C)(i), and for purposes of this para-
 16 graph, the “target date for publication” (re-
 17 ferred to in section 564(a)(5) of title 5, United
 18 States Code) shall be June 30, 2003.

19 (G) EFFECTIVE DATE.—The provisions of
 20 this paragraph shall apply to group health
 21 plans and health insurance issuers that offer
 22 health insurance coverage for plan or coverage
 23 years beginning on or after January 1, 2004.

24 (3) PAYMENT RATE.—In the case of covered
 25 items and services provided by—

1 (A) a participating provider, the payment
2 rate shall be at the agreed upon rate, or

3 (B) a nonparticipating provider, the pay-
4 ment rate shall be at the rate the plan or issuer
5 would normally pay for comparable services
6 under subparagraph (A).

7 (d) APPROVED CLINICAL TRIAL DEFINED.—

8 (1) IN GENERAL.—In this section, the term
9 “approved clinical trial” means a clinical research
10 study or clinical investigation approved or funded
11 (which may include funding through in-kind con-
12 tributions) by one or more of the following:

13 (A) The National Institutes of Health.

14 (B) A cooperative group or center of the
15 National Institutes of Health.

16 (C) Either of the following if the condi-
17 tions described in paragraph (2) are met:

18 (i) The Department of Veterans Af-
19 fairs.

20 (ii) The Department of Defense.

21 (2) CONDITIONS FOR DEPARTMENTS.—The
22 conditions described in this paragraph, for a study
23 or investigation conducted by a Department, are
24 that the study or investigation has been reviewed

1 and approved through a system of peer review that
 2 the Secretary determines—

3 (A) to be comparable to the system of peer
 4 review of studies and investigations used by the
 5 National Institutes of Health, and

6 (B) assures unbiased review of the highest
 7 scientific standards by qualified individuals who
 8 have no interest in the outcome of the review.

9 (e) CONSTRUCTION.—Nothing in this section shall be
 10 construed to preclude a plan or issuer from offering cov-
 11 erage that is broader than the coverage required under
 12 this section with respect to clinical trials.

13 (f) PLAN SATISFACTION OF CERTAIN REQUIRE-
 14 MENTS; RESPONSIBILITIES OF FIDUCIARIES.—

15 (1) IN GENERAL.—For purposes of this section,
 16 insofar as a group health plan provides benefits in
 17 the form of health insurance coverage through a
 18 health insurance issuer, the plan shall be treated as
 19 meeting the requirements of this section with respect
 20 to such benefits and not be considered as failing to
 21 meet such requirements because of a failure of the
 22 issuer to meet such requirements so long as the plan
 23 sponsor or its representatives did not cause such
 24 failure by the issuer.

1 (2) CONSTRUCTION.—Nothing in this section
2 shall be construed to affect or modify the respon-
3 sibilities of the fiduciaries of a group health plan
4 under part 4 of subtitle B.

5 (g) STUDY AND REPORT.—

6 (1) STUDY.—The Secretary shall study the im-
7 pact on group health plans and health insurance
8 issuers for covering routine patient care costs for in-
9 dividuals who are entitled to benefits under this sec-
10 tion and who are enrolled in an approved clinical
11 trial program.

12 (2) REPORT TO CONGRESS.—Not later than
13 January 1, 2006, the Secretary shall submit a re-
14 port to Congress that contains an assessment of—

15 (A) any incremental cost to group health
16 plans and health insurance issuers resulting
17 from the provisions of this section;

18 (B) a projection of expenditures to such
19 plans and issuers resulting from this section;
20 and

21 (C) any impact on premiums resulting
22 from this section.

1 **SEC. 110. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
 2 **STAY FOR MASTECTOMIES AND LYMPH NODE**
 3 **DISSECTIONS FOR THE TREATMENT OF**
 4 **BREAST CANCER AND COVERAGE FOR SEC-**
 5 **ONDARY CONSULTATIONS.**

6 (a) INPATIENT CARE.—

7 (1) IN GENERAL.—A group health plan, and a
 8 health insurance issuer that offers health insurance
 9 coverage, that provides medical and surgical benefits
 10 shall ensure that inpatient coverage with respect to
 11 the treatment of breast cancer is provided for a pe-
 12 riod of time as is determined by the attending physi-
 13 cian, in consultation with the patient, to be medi-
 14 cally necessary and appropriate following—

15 (A) a mastectomy;

16 (B) a lumpectomy; or

17 (C) a lymph node dissection for the treat-
 18 ment of breast cancer.

19 (2) EXCEPTION.—Nothing in this section shall
 20 be construed as requiring the provision of inpatient
 21 coverage if the attending physician and patient de-
 22 termine that a shorter period of hospital stay is
 23 medically appropriate.

24 (b) PROHIBITION ON CERTAIN MODIFICATIONS.—In
 25 implementing the requirements of this section, a group
 26 health plan, and a health insurance issuer that offers

1 health insurance coverage, may not modify the terms and
2 conditions of coverage based on the determination by a
3 participant, beneficiary, or enrollee to request less than
4 the minimum coverage required under subsection (a).

5 (c) SECONDARY CONSULTATIONS.—

6 (1) IN GENERAL.—A group health plan, and a
7 health insurance issuer that offers health insurance
8 coverage, that provides coverage with respect to
9 medical and surgical services provided in relation to
10 the diagnosis and treatment of cancer shall ensure
11 that full coverage is provided for secondary consulta-
12 tions by specialists in the appropriate medical fields
13 (including pathology, radiology, and oncology) to
14 confirm or refute such diagnosis. Such plan or issuer
15 shall ensure that full coverage is provided for such
16 secondary consultation whether such consultation is
17 based on a positive or negative initial diagnosis. In
18 any case in which the attending physician certifies in
19 writing that services necessary for such a secondary
20 consultation are not sufficiently available from spe-
21 cialists operating under the plan or coverage with re-
22 spect to whose services coverage is otherwise pro-
23 vided under such plan or by such issuer, such plan
24 or issuer shall ensure that coverage is provided with
25 respect to the services necessary for the secondary

1 consultation with any other specialist selected by the
 2 attending physician for such purpose at no addi-
 3 tional cost to the individual beyond that which the
 4 individual would have paid if the specialist was par-
 5 ticipating in the network of the plan or issuer.

6 (2) EXCEPTION.—Nothing in paragraph (1)
 7 shall be construed as requiring the provision of sec-
 8 ondary consultations where the patient determines
 9 not to seek such a consultation.

10 (d) PROHIBITION ON PENALTIES OR INCENTIVES.—
 11 A group health plan, and a health insurance issuer that
 12 offers health insurance coverage, may not—

13 (1) penalize or otherwise reduce or limit the re-
 14 imbursement of a provider or specialist because the
 15 provider or specialist provided care to a participant,
 16 beneficiary, or enrollee in accordance with this sec-
 17 tion;

18 (2) provide financial or other incentives to a
 19 physician or specialist to induce the physician or
 20 specialist to keep the length of inpatient stays of pa-
 21 tients following a mastectomy, lumpectomy, or a
 22 lymph node dissection for the treatment of breast
 23 cancer below certain limits or to limit referrals for
 24 secondary consultations; or

1 (3) provide financial or other incentives to a
 2 physician or specialist to induce the physician or
 3 specialist to refrain from referring a participant,
 4 beneficiary, or enrollee for a secondary consultation
 5 that would otherwise be covered by the plan or cov-
 6 erage involved under subsection (c).

7 **SEC. 111. PROHIBITION OF DISCRIMINATION AGAINST PRO-**
 8 **VIDERS BASED ON LICENSURE.**

9 (a) IN GENERAL.—A group health plan, and a health
 10 insurance issuer that offers health insurance coverage,
 11 shall not discriminate with respect to participation or in-
 12 demnification as to any provider who is acting within the
 13 scope of the provider’s license or certification under appli-
 14 cable State law, solely on the basis of such license or cer-
 15 tification.

16 (b) CONSTRUCTION.—Subsection (a) shall not be
 17 construed—

18 (1) as requiring the coverage under a group
 19 health plan or health insurance coverage, of a par-
 20 ticular benefit or service or to prohibit a plan or
 21 issuer from including providers only to the extent
 22 necessary to meet the needs of the plan’s or issuer’s
 23 participants, beneficiaries, or enrollees or from es-
 24 tablishing any measure designed to maintain quality

1 and control costs consistent with the responsibilities
 2 of the plan or issuer;

3 (2) to override any State licensure or scope-of-
 4 practice law; or

5 (3) as requiring a plan or issuer that offers net-
 6 work coverage to include for participation every will-
 7 ing provider who meets the terms and conditions of
 8 the plan or coverage.

9 **SEC. 112. GENERALLY APPLICABLE PROVISION.**

10 Notwithstanding section 102, in the case of a group
 11 health plan, and a health insurance issuer that offers
 12 health insurance coverage, that provides benefits under 2
 13 or more coverage options, the requirements of this subpart
 14 shall apply separately with respect to each coverage op-
 15 tion.

16 **Subtitle B—Right to Information**
 17 **About Plans and Providers**

18 **SEC. 121. HEALTH PLAN INFORMATION.**

19 (a) REQUIREMENT.—

20 (1) DISCLOSURE.—

21 (A) IN GENERAL.—A group health plan,
 22 and a health insurance issuer that offers health
 23 insurance coverage, shall provide for the disclo-
 24 sure of the information described in subsection

1 (b) to participants, beneficiaries, and
2 enrollees—

3 (i) at the time of the initial enrollment
4 of the participant, beneficiary, or enrollee
5 under the plan or coverage;

6 (ii) on an annual basis after
7 enrollment—

8 (I) in conjunction with the elec-
9 tion period of the plan or coverage if
10 the plan or coverage has such an elec-
11 tion period; or

12 (II) in the case of a plan or cov-
13 erage that does not have an election
14 period, in conjunction with the begin-
15 ning of the plan or coverage year; and

16 (iii) in the case of any material reduc-
17 tion to the benefits or information de-
18 scribed in paragraphs (1), (2) and (3) of
19 subsection (b), in the form of a summary
20 notice provided not later than the date on
21 which the reduction takes effect.

22 (B) PARTICIPANTS, BENEFICIARIES, OR
23 ENROLLEES.—The disclosure required under
24 subparagraph (A) shall be provided—

1 (i)(I) jointly to each participant and
 2 beneficiary who reside at the same address;

3 or

4 (II) in the case of a beneficiary who
 5 does not reside at the same address as the
 6 participant, separately to the participant
 7 and such beneficiary; and

8 (ii) to each enrollee.

9 (2) RULE OF CONSTRUCTION.—Nothing in this
 10 section shall be construed to prevent a group health
 11 plan sponsor and health insurance issuer from enter-
 12 ing into an agreement under which either the plan
 13 sponsor or the issuer agrees to assume responsibility
 14 for compliance with the requirements of this section,
 15 in whole or in part, and the party delegating such
 16 responsibility is released from liability for compli-
 17 ance with the requirements that are assumed by the
 18 other party, to the extent the party delegating such
 19 responsibility did not cause such noncompliance.

20 (3) PROVISION OF INFORMATION.—Information
 21 shall be provided to participants, beneficiaries, and
 22 enrollees under this section at the last known ad-
 23 dress maintained by the plan or issuer with respect
 24 to such participants, beneficiaries, or enrollees, to
 25 the extent that such information is provided to par-

1 ticipants, beneficiaries, or enrollees via the United
 2 States Postal Service or other private delivery serv-
 3 ice.

4 (b) REQUIRED INFORMATION.—The informational
 5 materials to be distributed under this section shall include
 6 for each option available under the group health plan or
 7 health insurance coverage the following:

8 (1) BENEFITS.—A description of the covered
 9 benefits, including—

10 (A) any in- and out-of-network benefits;

11 (B) specific preventative services covered
 12 under the plan or coverage if such services are
 13 covered;

14 (C) any benefit limitations, including any
 15 annual or lifetime benefit limits and any mone-
 16 tary limits or limits on the number of visits,
 17 days, or services, and any specific coverage ex-
 18 clusions; and

19 (D) any definition of medical necessity
 20 used in making coverage determinations by the
 21 plan, issuer, or claims administrator.

22 (2) COST SHARING.—A description of any cost-
 23 sharing requirements, including—

24 (A) any premiums, deductibles, coinsur-
 25 ance, copayment amounts, and liability for bal-

1 ance billing above any reasonable and cus-
 2 tomary charges, for which the participant, bene-
 3 ficiary, or enrollee will be responsible under
 4 each option available under the plan;

5 (B) any maximum out-of-pocket expense
 6 for which the participant, beneficiary, or en-
 7 rollee may be liable;

8 (C) any cost-sharing requirements for out-
 9 of-network benefits or services received from
 10 nonparticipating providers; and

11 (D) any additional cost-sharing or charges
 12 for benefits and services that are furnished
 13 without meeting applicable plan or coverage re-
 14 quirements, such as prior authorization or
 15 precertification.

16 (3) SERVICE AREA.—A description of the plan
 17 or issuer's service area, including the provision of
 18 any out-of-area coverage.

19 (4) PARTICIPATING PROVIDERS.—A directory of
 20 participating providers (to the extent a plan or
 21 issuer provides coverage through a network of pro-
 22 viders) that includes, at a minimum, the name, ad-
 23 dress, and telephone number of each participating
 24 provider, and information about how to inquire

1 whether a participating provider is currently accept-
2 ing new patients.

3 (5) CHOICE OF PRIMARY CARE PROVIDER.—A
4 description of any requirements and procedures to
5 be used by participants, beneficiaries, and enrollees
6 in selecting, accessing, or changing their primary
7 care provider, including providers both within and
8 outside of the network (if the plan or issuer permits
9 out-of-network services), and the right to select a pe-
10 diatrician as a primary care provider under section
11 104 for a participant, beneficiary, or enrollee who is
12 a child if such section applies.

13 (6) PREAUTHORIZATION REQUIREMENTS.—A
14 description of the requirements and procedures to be
15 used to obtain preauthorization for health services,
16 if such preauthorization is required.

17 (7) EXPERIMENTAL AND INVESTIGATIONAL
18 TREATMENTS.—A description of the process for de-
19 termining whether a particular item, service, or
20 treatment is considered experimental or investiga-
21 tional, and the circumstances under which such
22 treatments are covered by the plan or issuer.

23 (8) SPECIALTY CARE.—A description of the re-
24 quirements and procedures to be used by partici-
25 pants, beneficiaries, and enrollees in accessing spe-

1 cialty care and obtaining referrals to participating
2 and nonparticipating specialists, including the right
3 to timely coverage for access to specialists care
4 under section 105 if such section applies.

5 (9) CLINICAL TRIALS.—A description the cir-
6 cumstances and conditions under which participation
7 in clinical trials is covered under the terms and con-
8 ditions of the plan or coverage, and the right to ob-
9 tain coverage for approved cancer clinical trials
10 under section 109 if such section applies.

11 (10) PRESCRIPTION DRUGS.—To the extent the
12 plan or issuer provides coverage for prescription
13 drugs, a statement of whether such coverage is lim-
14 ited to drugs included in a formulary, a description
15 of any provisions and cost-sharing required for ob-
16 taining on- and off-formulary medications, and a de-
17 scription of the rights of participants, beneficiaries,
18 and enrollees in obtaining access to access to pre-
19 scription drugs under section 107 if such section ap-
20 plies.

21 (11) EMERGENCY SERVICES.—A summary of
22 the rules and procedures for accessing emergency
23 services, including the right of a participant, bene-
24 ficiary, or enrollee to obtain emergency services
25 under the prudent layperson standard under section

1 101, if such section applies, and any educational in-
2 formation that the plan or issuer may provide re-
3 garding the appropriate use of emergency services.

4 (12) CLAIMS AND APPEALS.—A description of
5 the plan or issuer’s rules and procedures pertaining
6 to claims and appeals, a description of the rights of
7 participants, beneficiaries, or enrollees under sec-
8 tions 503, 503A and 503B of the Employee Retirement
9 Income Security Act of 1974 (or sections
10 2707(b) and 2753(b) of the Public Health Service
11 with respect to non-Federal governmental plans and
12 individual health insurance coverage) in obtaining
13 covered benefits, filing a claim for benefits, and ap-
14 pealing coverage decisions internally and externally
15 (including telephone numbers and mailing addresses
16 of the appropriate authority), and a description of
17 any additional legal rights and remedies available
18 under section 502 of the Employee Retirement In-
19 come Security Act of 1974.

20 (13) ADVANCE DIRECTIVES AND ORGAN DONA-
21 TION.—A description of procedures for advance di-
22 rectives and organ donation decisions if the plan or
23 issuer maintains such procedures.

24 (14) INFORMATION ON PLANS AND ISSUERS.—
25 The name, mailing address, and telephone number

1 or numbers of the plan administrator and the issuer
2 to be used by participants, beneficiaries, and enroll-
3 ees seeking information about plan or coverage bene-
4 fits and services, payment of a claim, or authoriza-
5 tion for services and treatment. The name of the
6 designated decision-maker (or decision-makers) ap-
7 pointed under section 502(n)(2) of the Employee
8 Retirement Income Security Act of 1974 for pur-
9 poses of making final determinations under section
10 503A of such Act and approving coverage pursuant
11 to the written determination of an independent med-
12 ical reviewer under section 503B of such Act. Notice
13 of whether the benefits under the plan are provided
14 under a contract or policy of insurance issued by an
15 issuer, or whether benefits are provided directly by
16 the plan sponsor who bears the insurance risk.

17 (15) TRANSLATION SERVICES.—A summary de-
18 scription of any translation or interpretation services
19 (including the availability of printed information in
20 languages other than English, audio tapes, or infor-
21 mation in Braille) that are available for non-English
22 speakers and participants, beneficiaries, and enroll-
23 ees with communication disabilities and a description
24 of how to access these items or services.

1 (16) ACCREDITATION INFORMATION.—Any in-
2 formation that is made public by accrediting organi-
3 zations in the process of accreditation if the plan or
4 issuer is accredited, or any additional quality indica-
5 tors (such as the results of enrollee satisfaction sur-
6 veys) that the plan or issuer makes public or makes
7 available to participants, beneficiaries, and enrollees.

8 (17) NOTICE OF REQUIREMENTS.—A descrip-
9 tion of any rights of participants, beneficiaries, and
10 enrollees that are established by this Act (excluding
11 those described in paragraphs (1) through (16)) if
12 such rights apply. The description required under
13 this paragraph may be combined with the notices re-
14 quired under sections 711(d), 713(b), or 606(a)(1)
15 of the Employee Retirement Income Security Act of
16 1974, and with any other notice provision that the
17 Secretary determines may be combined.

18 (18) COMPENSATION METHODS.—A summary
19 description of the methods (including capitation, fee-
20 for-service, salary, withholds, bonuses, bundled pay-
21 ments, per diem, or a combination thereof) used for
22 compensating participating health care professionals
23 (including primary care providers and specialists)
24 and facilities in connection with the provision of
25 health care under the plan or coverage. The require-

1 ment of this paragraph shall not be construed as re-
2 quiring plans or issuers to provide information con-
3 cerning proprietary payment methodology.

4 (19) AVAILABILITY OF ADDITIONAL INFORMA-
5 TION.—A statement that the information described
6 in subsection (c), and instructions on obtaining such
7 information (including telephone numbers and, if
8 available, Internet websites), shall be made available
9 upon request.

10 (c) ADDITIONAL INFORMATION.—The informational
11 materials to be provided upon the request of a participant,
12 beneficiary, or enrollees shall include for each option avail-
13 able under a group health plan or health insurance cov-
14 erage the following:

15 (1) STATUS OF PROVIDERS.—The State licen-
16 sure status of the plan or issuer's participating
17 health care professionals and participating health
18 care facilities, and, if available, the education, train-
19 ing, specialty qualifications or certifications of such
20 professionals.

21 (2) PRESCRIPTION DRUGS.—Information about
22 whether a specific prescription medication is in-
23 cluded in the formulary of the plan or issuer, if the
24 plan or issuer uses a defined formulary.

1 (3) EXTERNAL APPEALS INFORMATION.—Ag-
2 gregate information on the number and outcomes of
3 external medical reviews, relative to the sample size
4 (such as the number of covered lives) determined for
5 the plan or issuer’s book of business.

6 (d) MANNER OF DISCLOSURE.—The information de-
7 scribed in this section shall be disclosed in an accessible
8 medium and format that is calculated to be understood
9 by the average participant.

10 (e) RULES OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to prohibit a group health plan,
12 or a health insurance issuer that offers health insurance
13 coverage, from—

14 (1) distributing any other additional informa-
15 tion determined by the plan or issuer to be impor-
16 tant or necessary in assisting participants, bene-
17 ficiaries, and enrollees in the selection of a health
18 plan; and

19 (2) complying with the provisions of this section
20 by providing information in brochures, through the
21 Internet or other electronic media, or through other
22 similar means, so long as participants, beneficiaries,
23 and enrollees are provided with an opportunity to re-
24 quest that informational materials be provided in
25 printed form.

1 (f) CONFORMING REGULATIONS.—The Secretary
2 shall issue regulations to coordinate the requirements on
3 group health plans and health insurance issuers under this
4 section with the requirements imposed under part 1, to
5 reduce duplication with respect to any information that
6 is required to be provided under any such requirements.

7 (g) SECRETARIAL ENFORCEMENT AUTHORITY.—

8 (1) IN GENERAL.—The Secretary of Health and
9 Human Services or the Secretary of Labor (as ap-
10 propriate) may assess a civil monetary penalty
11 against the administrator of a plan or issuer in con-
12 nection with the failure of the plan or issuer to com-
13 ply with the requirements of this section.

14 (2) AMOUNT OF PENALTY.—

15 (A) IN GENERAL.—The amount of the pen-
16 alty to be imposed under paragraph (1) shall
17 not exceed \$100 for each day for each partici-
18 pant, beneficiary, or enrollee with respect to
19 which the failure to comply with the require-
20 ments of this section occurs.

21 (B) INCREASE IN AMOUNT.—The amount
22 referred to in subparagraph (A) shall be in-
23 creased or decreased, for each calendar year
24 that ends after December 31, 2001, by the
25 same percentage as the percentage by which the

1 medical care expenditure category of the Con-
 2 sumer Price Index for All Urban Consumers
 3 (United States city average), published by the
 4 Bureau of Labor Statistics, for September of
 5 the preceding calendar year has increased or
 6 decreased from the such Index for September of
 7 2001.

8 (3) FAILURE DEFINED.—For purposes of this
 9 subsection, a plan or issuer shall have failed to com-
 10 ply with the requirements of this section with re-
 11 spect to a participant, beneficiary, or enrollee if the
 12 plan or issuer failed or refused to comply with the
 13 requirements of this section within 30 days—

14 (A) of the date described in subsection

15 (a)(1)(A)(i);

16 (B) of the date described in subsection

17 (a)(1)(A)(ii); or

18 (C) of the date on which additional infor-
 19 mation was requested under subsection (c).

20 (h) CONFORMING AMENDMENTS.—

21 (1) Section 732(a) of the Employee Retirement
 22 Income Security Act of 1974 (29 U.S.C. 1191a(a))
 23 is amended by striking “section 711” and inserting
 24 “section 711 and section 121 of the Bipartisan Pa-
 25 tients’ Bill of Rights Act of 2001”.

1 (2) Section 502(b)(3) of the Employee Retirement
 2 Income Security Act of 1974 (29 U.S.C.
 3 1132(b)(3)) is amended by striking “733(a)(1))”
 4 and inserting “733(a)(1)), except with respect to the
 5 requirements of section 121 of the Bipartisan Pa-
 6 tients’ Bill of Rights Act of 2001”.

7 **SEC. 122. INFORMATION ABOUT PROVIDERS.**

8 (a) STUDY.—The Secretary of Health and Human
 9 Services shall enter into a contract with the Institute of
 10 Medicine for the conduct of a study, and the submission
 11 to the Secretary of a report, that includes—

12 (1) an analysis of information concerning health
 13 care professionals that is currently available to pa-
 14 tients, consumers, States, and professional societies,
 15 nationally and on a State-by-State basis, including
 16 patient preferences with respect to information
 17 about such professionals and their competencies;

18 (2) an evaluation of the legal and other barriers
 19 to the sharing of information concerning health care
 20 professionals; and

21 (3) recommendations for the disclosure of infor-
 22 mation on health care professionals, including the
 23 competencies and professional qualifications of such
 24 practitioners, to better facilitate patient choice, qual-
 25 ity improvement, and market competition.

1 (b) REPORT.—Not later than 18 months after the
 2 date of enactment of this Act, the Secretary of Health and
 3 Human Services shall forward to the appropriate commit-
 4 tees of Congress a copy of the report and study conducted
 5 under subsection (a).

6 **SEC. 123. STUDY ON THE EFFECT OF PHYSICIAN COM-**
 7 **PENSATION METHODS.**

8 (a) STUDY AND REPORT.—

9 (1) IN GENERAL.—The Secretary shall enter
 10 into a contract with the Institute of Medicine for the
 11 conduct of a study in accordance with this section,
 12 to be submitted to the Secretary and the Secretary
 13 of Labor as provided for in paragraph (4).

14 (2) MATTERS TO BE STUDIED.—The study
 15 under paragraph (1) shall include—

16 (A) a study, including a survey if nec-
 17 essary, of physician compensation arrangements
 18 that are utilized in employer-sponsored group
 19 health plans (including group health plans
 20 sponsored by government and non-government
 21 employers) and commercial health insurance
 22 products, including—

23 (i) all types of compensation arrange-
 24 ments, including financial incentive and
 25 risk sharing arrangements and arrange-

1 ments that do not contain such incentives
2 and risk sharing, that reflect the com-
3 plexity of organizational relationships be-
4 tween health plans and physicians;

5 (ii) arrangements that are based on
6 factors such as utilization management,
7 cost control, quality improvement, and pa-
8 tient or enrollee satisfaction; and

9 (iii) arrangements between the plan or
10 issuer and provider, as well as down-
11 stream arrangements between providers
12 and sub-contracted providers;

13 (B) an analysis of the effect of such dif-
14 fering arrangements on physician behavior with
15 respect to the provision of medical care to pa-
16 tients, including whether and how such arrange-
17 ments affect the quality of patient care and the
18 ability of physicians to provide care that is
19 medically necessary and appropriate.

20 (3) STUDY DESIGN.—The Secretary shall con-
21 sult with the Director of the Agency for Healthcare
22 Research and Quality in preparing the scope of work
23 and study design with respect to the contract under
24 paragraph (1).

1 (4) REPORT.—Not later than 24 months
2 after the date of enactment of this Act, the Sec-
3 retary shall forward to the appropriate commit-
4 tees of Congress a copy of the report and study
5 conducted under subsection (a).

6 (b) RESEARCH.—

7 (1) IN GENERAL.—The Secretary, acting
8 through the Director of the Agency for Healthcare
9 Research and Quality, shall conduct and support re-
10 search to develop scientific evidence regarding the
11 effects of differing physician compensation methods
12 on physician behavior with respect to the provision
13 of medical care to patients, particularly issues relat-
14 ing to the quality of patient care and whether pa-
15 tients receive medically necessary and appropriate
16 care.

17 (2) AUTHORIZATION OF APPROPRIATIONS.—For
18 purposes of carrying out this section, there are au-
19 thorized to be appropriated such sums as may be
20 necessary.

1 **Subtitle C—Right to Hold Health**
 2 **Plans Accountable**

3 **SEC. 131. AMENDMENTS TO EMPLOYEE RETIREMENT IN-**
 4 **COME SECURITY ACT OF 1974.**

5 (a) IN GENERAL.—Part 5 of subtitle B of title I of
 6 the Employee Retirement Income Security Act of 1974 is
 7 amended by inserting after section 503 (29 U.S.C. 1133)
 8 the following:

9 **“SEC. 503A. CLAIMS AND INTERNAL APPEALS PROCEDURES**
 10 **FOR GROUP HEALTH PLANS.**

11 “(a) INITIAL CLAIM FOR BENEFITS UNDER GROUP
 12 HEALTH PLANS.—

13 “(1) PROCEDURES.—

14 “(A) IN GENERAL.—A group health plan,
 15 or health insurance issuer that offers health in-
 16 surance coverage in connection with a group
 17 health plan, shall ensure that procedures are in
 18 place for—

19 “(i) making a determination on an
 20 initial claim for benefits by a participant
 21 or beneficiary (or authorized representa-
 22 tive) regarding payment or coverage for
 23 items or services under the terms and con-
 24 ditions of the plan or coverage involved, in-
 25 cluding any cost-sharing amount that the

1 participant or beneficiary is required to
2 pay with respect to such claim for benefits;
3 and

4 “(ii) notifying a participant or bene-
5 ficiary (or authorized representative) and
6 the treating health care professional in-
7 volved regarding a determination on an ini-
8 tial claim for benefits made under the
9 terms and conditions of the plan or cov-
10 erage, including any cost-sharing amounts
11 that the participant or beneficiary may be
12 required to make with respect to such
13 claim for benefits, and of the right of the
14 participant or beneficiary to an internal
15 appeal under subsection (b).

16 “(B) ACCESS TO INFORMATION.—With re-
17 spect to an initial claim for benefits, the partici-
18 pant or beneficiary (or authorized representa-
19 tive) and the treating health care professional
20 (if any) shall provide the plan or issuer with ac-
21 cess to information requested by the plan or
22 issuer that is necessary to make a determina-
23 tion relating to the claim, not later than 5 busi-
24 ness days after the date on which the claim is

1 filed or to meet the applicable timelines under
 2 clauses (ii) and (iii) of paragraph (2)(A).

3 “(C) ORAL REQUESTS.—In the case of a
 4 claim for benefits involving an expedited or con-
 5 current determination, a participant or bene-
 6 ficiary (or authorized representative) may make
 7 an initial claim for benefits orally, but a group
 8 health plan, or health insurance issuer that of-
 9 fers health insurance coverage in connection
 10 with a group health plan, may require that the
 11 participant or beneficiary (or authorized rep-
 12 resentative) provide written confirmation of
 13 such request in a timely manner.

14 “(2) TIMELINE FOR MAKING DETERMINA-
 15 TIONS.—

16 “(A) PRIOR AUTHORIZATION DETERMINA-
 17 TION.—

18 “(i) IN GENERAL.—A group health
 19 plan, or health insurance issuer that offers
 20 health insurance coverage in connection
 21 with a group health plan, shall maintain
 22 procedures to ensure that a prior author-
 23 ization determination on a claim for bene-
 24 fits is made within 14 business days from
 25 the date on which the plan or issuer re-

1 ceives information that is reasonably nec-
2 essary to enable the plan or issuer to make
3 a determination on the request for prior
4 authorization, but in no case shall such de-
5 termination be made later than 28 busi-
6 ness days after the receipt of the claim for
7 benefits.

8 “(ii) EXPEDITED DETERMINATION.—
9 Notwithstanding clause (i), a group health
10 plan, or health insurance issuer that offers
11 health insurance coverage in connection
12 with a group health plan, shall maintain
13 procedures for expediting a prior author-
14 ization determination on a claim for bene-
15 fits described in such clause when a re-
16 quest for such an expedited determination
17 is made by a participant or beneficiary (or
18 authorized representative) at any time dur-
19 ing the process for making a determination
20 and the treating health care professional
21 substantiates, with the request, that a de-
22 termination under the procedures described
23 in clause (i) would seriously jeopardize the
24 life or health of the participant or bene-
25 ficiary. Such determination shall be made

1 within 72 hours after a request is received
2 by the plan or issuer under this clause.

3 “(iii) CONCURRENT DETERMINA-
4 TIONS.—A group health plan, or health in-
5 surance issuer that offers health insurance
6 coverage in connection with a group health
7 plan, shall maintain procedures to ensure
8 that a concurrent determination on a claim
9 for benefits that results in a discontinu-
10 ation of inpatient care is made within 24
11 hours after the receipt of the claim for
12 benefits.

13 “(B) RETROSPECTIVE DETERMINATION.—
14 A group health plan, or health insurance issuer
15 that offers health insurance coverage in connec-
16 tion with a group health plan, shall maintain
17 procedures to ensure that a retrospective deter-
18 mination on a claim for benefits is made within
19 30 business days of the date on which the plan
20 or issuer receives information that is reasonably
21 necessary to enable the plan or issuer to make
22 a determination on the claim, but in no case
23 shall such determination be made later than 60
24 business days after the receipt of the claim for
25 benefits.

1 “(3) NOTICE OF A DENIAL OF A CLAIM FOR
2 BENEFITS.—Written notice of a denial made under
3 an initial claim for benefits shall be issued to the
4 participant or beneficiary (or authorized representa-
5 tive) and the treating health care professional not
6 later than 2 business days after the determination
7 (or within the 72-hour or 24-hour period referred to
8 in clauses (ii) and (iii) of paragraph (2)(A) if appli-
9 cable).

10 “(4) REQUIREMENTS OF NOTICE OF DETER-
11 MINATIONS.—The written notice of a denial of a
12 claim for benefits determination under paragraph
13 (3) shall include—

14 “(A) the reasons for the determination (in-
15 cluding a summary of the clinical or scientific-
16 evidence based rationale used in making the de-
17 termination and instruction on obtaining a
18 more complete description written in a manner
19 calculated to be understood by the average par-
20 ticipant);

21 “(B) the procedures for obtaining addi-
22 tional information concerning the determina-
23 tion; and

24 “(C) notification of the right to appeal the
25 determination and instructions on how to ini-

1 tiate an appeal in accordance with subsection
2 (b).

3 “(b) INTERNAL APPEAL OF A DENIAL OF A CLAIM
4 FOR BENEFITS.—

5 “(1) RIGHT TO INTERNAL APPEAL.—

6 “(A) IN GENERAL.—A participant or bene-
7 ficiary (or authorized representative) may ap-
8 peal any denial of a claim for benefits under
9 subsection (a) under the procedures described
10 in this subsection.

11 “(B) TIME FOR APPEAL.—A group health
12 plan, or health insurance issuer that offers
13 health insurance coverage in connection with a
14 group health plan, shall ensure that a partici-
15 pant or beneficiary (or authorized representa-
16 tive) has a period of not less than 60 days be-
17 ginning on the date of a denial of a claim for
18 benefits under subsection (a) in which to appeal
19 such denial under this subsection.

20 “(C) FAILURE TO ACT.—The failure of a
21 plan or issuer to issue a determination on a
22 claim for benefits under subsection (a) within
23 the applicable timeline established for such a
24 determination under such subsection shall be
25 treated as a denial of a claim for benefits for

1 purposes of proceeding to internal review under
 2 this subsection.

3 “(D) PLAN WAIVER OF INTERNAL RE-
 4 VIEW.—A group health plan, or health insur-
 5 ance issuer that offers health insurance cov-
 6 erage in connection with a group health plan,
 7 may waive the internal review process under
 8 this subsection and permit a participant or ben-
 9 eficiary (or authorized representative) to pro-
 10 ceed directly to external review under section
 11 503B.

12 “(2) TIMELINES FOR MAKING DETERMINA-
 13 TIONS.—

14 “(A) ORAL REQUESTS.—In the case of an
 15 appeal of a denial of a claim for benefits under
 16 this subsection that involves an expedited or
 17 concurrent determination, a participant or ben-
 18 eficiary (or authorized representative) may re-
 19 quest such appeal orally, but a group health
 20 plan, or health insurance issuer that offers
 21 health insurance coverage in connection with a
 22 group health plan, may require that the partici-
 23 pant or beneficiary (or authorized representa-
 24 tive) provide written confirmation of such re-
 25 quest in a timely manner.

1 “(B) ACCESS TO INFORMATION.—With re-
2 spect to an appeal of a denial of a claim for
3 benefits, the participant or beneficiary (or au-
4 thorized representative) and the treating health
5 care professional (if any) shall provide the plan
6 or issuer with access to information requested
7 by the plan or issuer that is necessary to make
8 a determination relating to the appeal, not later
9 than 5 business days after the date on which
10 the request for the appeal is filed or to meet the
11 applicable timelines under clauses (ii) and (iii)
12 of subparagraph (C).

13 “(C) PRIOR AUTHORIZATION DETERMINA-
14 TIONS.—

15 “(i) IN GENERAL.—A group health
16 plan, or health insurance issuer that offers
17 health insurance coverage in connection
18 with a group health plan, shall maintain
19 procedures to ensure that a determination
20 on an appeal of a denial of a claim for ben-
21 efits under this subsection is made within
22 14 business days after the date on which
23 the plan or issuer receives information that
24 is reasonably necessary to enable the plan
25 or issuer to make a determination on the

1 appeal, but in no case shall such deter-
2 mination be made later than 28 business
3 days after the receipt of the request for the
4 appeal.

5 “(ii) EXPEDITED DETERMINATION.—
6 Notwithstanding clause (i), a group health
7 plan, or health insurance issuer that offers
8 health insurance coverage in connection
9 with a group health plan, shall maintain
10 procedures for expediting a prior author-
11 ization determination on an appeal of a de-
12 nial of a claim for benefits described in
13 clause (i), when a request for such an ex-
14 pedited determination is made by a partici-
15 pant or beneficiary (or authorized rep-
16 resentative) at any time during the process
17 for making a determination and the treat-
18 ing health care professional substantiates,
19 with the request, that a determination
20 under the procedures described in clause
21 (i) would seriously jeopardize the life or
22 health of the participant or beneficiary.
23 Such determination shall be made not later
24 than 72 hours after the request for such

1 appeal is received by the plan or issuer
2 under this clause.

3 “(iii) CONCURRENT DETERMINA-
4 TIONS.—A group health plan, or health in-
5 surance issuer that offers health insurance
6 coverage in connection with a group health
7 plan, shall maintain procedures to ensure
8 that a concurrent determination on an ap-
9 peal of a denial of a claim for benefits that
10 results in a discontinuation of inpatient
11 care is made within 24 hours after the re-
12 ceipt of the request for appeal.

13 “(B) RETROSPECTIVE DETERMINATION.—
14 A group health plan, or health insurance issuer
15 that offers health insurance coverage in connec-
16 tion with a group health plan, shall maintain
17 procedures to ensure that a retrospective deter-
18 mination on an appeal of a claim for benefits is
19 made within 30 business days of the date on
20 which the plan or issuer receives necessary in-
21 formation that is reasonably required by the
22 plan or issuer to make a determination on the
23 appeal, but in no case shall such determination
24 be made later than 60 business days after the
25 receipt of the request for the appeal.

1 “(3) CONDUCT OF REVIEW.—

2 “(A) IN GENERAL.—A review of a denial
3 of a claim for benefits under this subsection
4 shall be conducted by an individual with appro-
5 priate expertise who was not directly involved in
6 the initial determination.

7 “(B) REVIEW OF MEDICAL DECISIONS BY
8 PHYSICIANS.—A review of an appeal of a denial
9 of a claim for benefits that is based on a lack
10 of medical necessity and appropriateness, or
11 based on an experimental or investigational
12 treatment, or requires an evaluation of medical
13 facts, shall be made by a physician with appro-
14 priate expertise, including age-appropriate ex-
15 pertise, who was not involved in the initial de-
16 termination.

17 “(4) NOTICE OF DETERMINATION.—

18 “(A) IN GENERAL.—Written notice of a
19 determination made under an internal appeal of
20 a denial of a claim for benefits shall be issued
21 to the participant or beneficiary (or authorized
22 representative) and the treating health care
23 professional not later than 2 business days after
24 the completion of the review (or within the 72-

1 hour or 24-hour period referred to in paragraph
2 (2) if applicable).

3 “(B) FINAL DETERMINATION.—The deci-
4 sion by a plan or issuer under this subsection
5 shall be treated as the final determination of
6 the plan or issuer on a denial of a claim for
7 benefits. The failure of a plan or issuer to issue
8 a determination on an appeal of a denial of a
9 claim for benefits under this subsection within
10 the applicable timeline established for such a
11 determination shall be treated as a final deter-
12 mination on an appeal of a denial of a claim for
13 benefits for purposes of proceeding to external
14 review under section 503B.

15 “(C) REQUIREMENTS OF NOTICE.—With
16 respect to a determination made under this sub-
17 section, the notice described in subparagraph
18 (A) shall include—

19 “(i) the reasons for the determination
20 (including a summary of the clinical or sci-
21 entific-evidence based rationale used in
22 making the determination and instruction
23 on obtaining a more complete description
24 written in a manner calculated to be un-
25 derstood by the average participant);

1 “(ii) the procedures for obtaining ad-
 2 ditional information concerning the deter-
 3 mination; and

4 “(iii) notification of the right to an
 5 independent external review under section
 6 503B and instructions on how to initiate
 7 such a review.

8 “(c) DEFINITIONS.—The definitions contained in sec-
 9 tion 503B(i) shall apply for purposes of this section.

10 **“SEC. 503B. INDEPENDENT EXTERNAL APPEALS PROCE-
 11 DURES FOR GROUP HEALTH PLANS.**

12 “(a) RIGHT TO EXTERNAL APPEAL.—A group health
 13 plan, and a health insurance issuer that offers health in-
 14 surance coverage in connection with a group health plan,
 15 shall provide in accordance with this section participants
 16 and beneficiaries (or authorized representatives) with ac-
 17 cess to an independent external review for any denial of
 18 a claim for benefits.

19 “(b) INITIATION OF THE INDEPENDENT EXTERNAL
 20 REVIEW PROCESS.—

21 “(1) TIME TO FILE.—A request for an inde-
 22 pendent external review under this section shall be
 23 filed with the plan or issuer not later than 60 busi-
 24 ness days after the date on which the participant or
 25 beneficiary receives notice of the denial under sec-

tion 503A(b)(4) or the date on which the internal review is waived by the plan or issuer under section 503A(b)(1)(D).

“(2) FILING OF REQUEST.—

“(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, may—

“(i) except as provided in subparagraph (B)(i), require that a request for review be in writing;

“(ii) limit the filing of such a request to the participant or beneficiary involved (or an authorized representative);

“(iii) except if waived by the plan or issuer under section 503A(b)(1)(D), condition access to an independent external review under this section upon a final determination of a denial of a claim for benefits under the internal review procedure under section 503A;

“(iv) except as provided in subparagraph (B)(ii), require payment of a filing

1 fee to the plan or issuer of a sum that does
2 not exceed \$50; and

3 “(v) require that a request for review
4 include the consent of the participant or
5 beneficiary (or authorized representative)
6 for the release of medical information or
7 records of the participant or beneficiary to
8 the qualified external review entity for pur-
9 poses of conducting external review activi-
10 ties.

11 “(B) REQUIREMENTS AND EXCEPTION RE-
12 LATING TO GENERAL RULE.—

13 “(i) ORAL REQUESTS PERMITTED IN
14 EXPEDITED OR CONCURRENT CASES.—In
15 the case of an expedited or concurrent ex-
16 ternal review as provided for under sub-
17 section (e), the request may be made oral-
18 ly. In such case a written confirmation of
19 such request shall be made in a timely
20 manner. Such written confirmation shall be
21 treated as a consent for purposes of sub-
22 paragraph (A)(v).

23 “(ii) EXCEPTION TO FILING FEE RE-
24 QUIREMENT.—

1 “(I) INDIGENCY.—Payment of a
2 filing fee shall not be required under
3 subparagraph (A)(iv) where there is a
4 certification (in a form and manner
5 specified in guidelines established by
6 the Secretary) that the participant or
7 beneficiary is indigent (as defined in
8 such guidelines). In establishing
9 guidelines under this subclause, the
10 Secretary shall ensure that the guide-
11 lines relating to indigency are con-
12 sistent with the poverty guidelines
13 used by the Secretary of Health and
14 Human Services under title XIX of
15 the Social Security Act.

16 “(II) FEE NOT REQUIRED.—Pay-
17 ment of a filing fee shall not be re-
18 quired under subparagraph (A)(iv) if
19 the plan or issuer waives the internal
20 appeals process under section
21 503A(b)(1)(D).

22 “(III) REFUNDING OF FEE.—
23 The filing fee paid under subpara-
24 graph (A)(iv) shall be refunded if the
25 determination under the independent

1 external review is to reverse the denial
2 which is the subject of the review.

3 “(IV) INCREASE IN AMOUNT.—

4 The amount referred to in subclause
5 (I) shall be increased or decreased, for
6 each calendar year that ends after De-
7 cember 31, 2002, by the same per-
8 centage as the percentage by which
9 the Consumer Price Index for All
10 Urban Consumers (United States city
11 average), published by the Bureau of
12 Labor Statistics, for September of the
13 preceding calendar year has increased
14 or decreased from the such Index for
15 September of 2002.

16 “(c) REFERRAL TO QUALIFIED EXTERNAL REVIEW
17 ENTITY UPON REQUEST.—

18 “(1) IN GENERAL.—Upon the filing of a re-
19 quest for independent external review with the group
20 health plan, or health insurance issuer that offers
21 health insurance coverage in connection with a group
22 health plan, the plan or issuer shall refer such re-
23 quest to a qualified external review entity selected in
24 accordance with this section.

1 “(2) ACCESS TO PLAN OR ISSUER AND HEALTH
 2 PROFESSIONAL INFORMATION.—With respect to an
 3 independent external review conducted under this
 4 section, the participant or beneficiary (or authorized
 5 representative), the plan or issuer, and the treating
 6 health care professional (if any) shall provide the ex-
 7 ternal review entity with access to information re-
 8 quested by the external review entity that is nec-
 9 essary to conduct a review under this section, as de-
 10 termined by the entity, not later than 5 business
 11 days after the date on which a request is referred to
 12 the qualified external review entity under paragraph
 13 (1), or earlier as determined appropriate by the enti-
 14 ty to meet the applicable timelines under clauses (ii)
 15 and (iii) of subsection (e)(1)(A).

16 “(3) SCREENING OF REQUESTS BY QUALIFIED
 17 EXTERNAL REVIEW ENTITIES.—

18 “(A) IN GENERAL.—With respect to a re-
 19 quest referred to a qualified external review en-
 20 tity under paragraph (1) relating to a denial of
 21 a claim for benefits, the entity shall refer such
 22 request for the conduct of an independent med-
 23 ical review unless the entity determines that—

24 “(i) any of the conditions described in
 25 subsection (b)(2)(A) have not been met;

1 “(ii) the thresholds described in sub-
2 paragraph (B) have not been met;

3 “(iii) the denial of the claim for bene-
4 fits does not involve a medically reviewable
5 decision under subsection (d)(2);

6 “(iv) the denial of the claim for bene-
7 fits relates to a decision regarding whether
8 an individual is a participant or beneficiary
9 who is enrolled under the terms of the plan
10 or coverage (including the applicability of
11 any waiting period under the plan or cov-
12 erage); or

13 “(v) the denial of the claim for bene-
14 fits is a decision as to the application of
15 cost-sharing requirements or the applica-
16 tion of a specific exclusion or express limi-
17 tation on the amount, duration, or scope of
18 coverage of items or services under the
19 terms and conditions of the plan or cov-
20 erage unless the decision is a denial de-
21 scribed in subsection (d)(2);

22 Upon making a determination that any of
23 clauses (i) through (v) applies with respect to
24 the request, the entity shall determine that the
25 denial of a claim for benefits involved is not eli-

gible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (D).

“(B) THRESHOLDS.—

“(i) IN GENERAL.—The thresholds described in this subparagraph are that—

“(I) the total amount payable under the plan or coverage for the item or service that was the subject of such denial exceeds \$100; or

“(II) a physician has asserted in writing that there is a significant risk of placing the life, health, or development of the participant or beneficiary in jeopardy if the denial of the claim for benefits is sustained.

“(ii) THRESHOLDS NOT APPLIED.—

The thresholds described in this subparagraph shall not apply if the plan or issuer involved waives the internal appeals process with respect to the denial of a claim for benefits involved under section 503A(b)(1)(D).

“(C) PROCESS FOR MAKING DETERMINATIONS.—

1 “(i) NO DEFERENCE TO PRIOR DE-
 2 TERMINATIONS.—In making determina-
 3 tions under subparagraph (A), there shall
 4 be no deference given to determinations
 5 made by the plan or issuer under section
 6 503A or the recommendation of a treating
 7 health care professional (if any).

8 “(ii) USE OF APPROPRIATE PER-
 9 SONNEL.—A qualified external review enti-
 10 ty shall use appropriately qualified per-
 11 sonnel to make determinations under this
 12 section.

13 “(D) NOTICES AND GENERAL TIMELINES
 14 FOR DETERMINATION.—

15 “(i) NOTICE IN CASE OF DENIAL OF
 16 REFERRAL.—If the entity under this para-
 17 graph does not make a referral to an inde-
 18 pendent medical reviewer, the entity shall
 19 provide notice to the plan or issuer, the
 20 participant or beneficiary (or authorized
 21 representative) filing the request, and the
 22 treating health care professional (if any)
 23 that the denial is not subject to inde-
 24 pendent medical review. Such notice—

1 “(I) shall be written (and, in ad-
2 dition, may be provided orally) in a
3 manner calculated to be understood
4 by an average participant;

5 “(II) shall include the reasons for
6 the determination; and

7 “(III) include any relevant terms
8 and conditions of the plan or cov-
9 erage.

10 “(ii) GENERAL TIMELINE FOR DETER-
11 MINATIONS.—Upon receipt of information
12 under paragraph (2), the qualified external
13 review entity, and if required the inde-
14 pendent medical reviewer, shall make a de-
15 termination within the overall timeline that
16 is applicable to the case under review as
17 described in subsection (e), except that if
18 the entity determines that a referral to an
19 independent medical reviewer is not re-
20 quired, the entity shall provide notice of
21 such determination to the participant or
22 beneficiary (or authorized representative)
23 within 2 business days of such determina-
24 tion.

25 “(d) INDEPENDENT MEDICAL REVIEW.—

1 “(1) IN GENERAL.—If a qualified external re-
2 view entity determines under subsection (c) that a
3 denial of a claim for benefits is eligible for inde-
4 pendent medical review, the entity shall refer the de-
5 nial involved to an independent medical reviewer for
6 the conduct of an independent medical review under
7 this subsection.

8 “(2) MEDICALLY REVIEWABLE DECISIONS.—A
9 denial described in this paragraph is one for which
10 the item or service that is the subject of the denial
11 would be a covered benefit under the terms and con-
12 ditions of the plan or coverage but for one (or more)
13 of the following determinations:

14 “(A) DENIALS BASED ON MEDICAL NECES-
15 SITY AND APPROPRIATENESS.—The basis of the
16 determination is that the item or service is not
17 medically necessary and appropriate.

18 “(B) DENIALS BASED ON EXPERIMENTAL
19 OR INVESTIGATIONAL TREATMENT.—The basis
20 of the determination is that the item or service
21 is experimental or investigational.

22 “(C) DENIALS OTHERWISE BASED ON AN
23 EVALUATION OF MEDICAL FACTS.—A deter-
24 mination that the item or service or condition
25 is not covered but an evaluation of the medical

1 facts by a health care professional in the spe-
 2 cific case involved is necessary to determine
 3 whether the item or service or condition is re-
 4 quired to be provided under the terms and con-
 5 ditions of the plan or coverage.

6 “(3) INDEPENDENT MEDICAL REVIEW DETER-
 7 MINATION.—

8 “(A) IN GENERAL.—An independent med-
 9 ical reviewer under this section shall make a
 10 new independent determination with respect
 11 to—

12 “(i) whether the item or service or
 13 condition that is the subject of the denial
 14 is covered under the terms and conditions
 15 of the plan or coverage; and

16 “(ii) based upon an affirmative deter-
 17 mination under clause (i), whether or not
 18 the denial of a claim for a benefit that is
 19 the subject of the review should be upheld
 20 or reversed.

21 “(B) STANDARD FOR DETERMINATION.—
 22 The independent medical reviewer’s determina-
 23 tion relating to the medical necessity and ap-
 24 propriateness, or the experimental or investiga-
 25 tion nature, or the evaluation of the medical

1 facts of the item, service, or condition shall be
2 based on the medical condition of the partici-
3 pant or beneficiary (including the medical
4 records of the participant or beneficiary) and
5 the valid, relevant scientific evidence and clin-
6 ical evidence, including peer-reviewed medical
7 literature or findings and including expert con-
8 sensus.

9 “(C) NO COVERAGE FOR EXCLUDED BENE-
10 FITS.—Nothing in this subsection shall be con-
11 strued to permit an independent medical re-
12 viewer to require that a group health plan, or
13 health insurance issuer that offers health insur-
14 ance coverage in connection with a group health
15 plan, provide coverage for items or services that
16 are specifically excluded or expressly limited
17 under the plan or coverage and that are not
18 covered regardless of any determination relating
19 to medical necessity and appropriateness, exper-
20 imental or investigational nature of the treat-
21 ment, or an evaluation of the medical facts in
22 the case involved.

23 “(D) EVIDENCE AND INFORMATION TO BE
24 USED IN MEDICAL REVIEWS.—In making a de-
25 termination under this subsection, the inde-

pendent medical reviewer shall also consider appropriate and available evidence and information, including the following:

“(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence or guidelines used by the plan or issuer in reaching such determination.

“(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by the treating health care professional in reaching such recommendation.

“(iii) Additional evidence or information obtained by the reviewer or submitted by the plan, issuer, participant or beneficiary (or an authorized representative), or treating health care professional.

“(iv) The plan or coverage document.

“(E) INDEPENDENT DETERMINATION.—In making the determination, the independent medical reviewer shall—

“(i) consider the claim under review without deference to the determinations made by the plan or issuer under section

1 503A or the recommendation of the treat-
 2 ing health care professional (if any); and

3 “(ii) consider, but not be bound by
 4 the definition used by the plan or issuer of
 5 ‘medically necessary and appropriate’, or
 6 ‘experimental or investigational’, or other
 7 equivalent terms that are used by the plan
 8 or issuer to describe medical necessity and
 9 appropriateness or experimental or inves-
 10 tigational nature of the treatment.

11 “(F) DETERMINATION OF INDEPENDENT
 12 MEDICAL REVIEWER.—An independent medical
 13 reviewer shall, in accordance with the deadlines
 14 described in subsection (e), prepare a written
 15 determination to uphold or reverse the denial
 16 under review and, in the case of a reversal, the
 17 timeframe within which the plan or issuer shall
 18 authorize coverage to comply with the deter-
 19 mination. Such written determination shall in-
 20 clude the specific reasons of the reviewer for
 21 such determination, including a summary of the
 22 clinical or scientific-evidence based rationale
 23 used in making the determination. The reviewer
 24 may provide the plan or issuer and the treating
 25 health care professional with additional rec-

1 ommendations in connection with such a deter-
 2 mination, but any such recommendations shall
 3 not be treated as part of the determination.

4 “(e) TIMELINES AND NOTIFICATIONS.—

5 “(1) TIMELINES FOR INDEPENDENT MEDICAL
 6 REVIEW.—

7 “(A) PRIOR AUTHORIZATION DETERMINA-
 8 TION.—

9 “(i) IN GENERAL.—The independent
 10 medical reviewer (or reviewers) shall make
 11 a determination on a denial of a claim for
 12 benefits that is referred to the reviewer
 13 under subsection (c)(3) not later than 14
 14 business days after the receipt of informa-
 15 tion under subsection (c)(2) if the review
 16 involves a prior authorization of items or
 17 services.

18 “(ii) EXPEDITED DETERMINATION.—
 19 Notwithstanding clause (i), the inde-
 20 pendent medical reviewer (or reviewers)
 21 shall make an expedited determination on
 22 a denial of a claim for benefits described in
 23 clause (i), when a request for such an ex-
 24 pedited determination is made by a partici-
 25 pant or beneficiary (or authorized rep-

representative) at any time during the process for making a determination, and the treating health care professional substantiates, with the request, that a determination under the timeline described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the receipt of information under subsection (c)(2).

“(iii) CONCURRENT DETERMINATION.—Notwithstanding clause (i), a review described in such subclause shall be completed not later than 24 hours after the receipt of information under subsection (c)(2) if the review involves a discontinuation of inpatient care.

“(B) RETROSPECTIVE DETERMINATION.—The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 30 business days after the receipt of information under subsection (c)(2).

1 “(2) NOTIFICATION OF DETERMINATION.—The
 2 external review entity shall ensure that the plan or
 3 issuer, the participant or beneficiary (or authorized
 4 representative) and the treating health care profes-
 5 sional (if any) receives a copy of the written deter-
 6 mination of the independent medical reviewer pre-
 7 pared under subsection (d)(3)(F). Nothing in this
 8 paragraph shall be construed as preventing an entity
 9 or reviewer from providing an initial oral notice of
 10 the reviewer’s determination.

11 “(3) FORM OF NOTICES.—Determinations and
 12 notices under this subsection shall be written in a
 13 manner calculated to be understood by an average
 14 participant.

15 “(4) TERMINATION OF EXTERNAL REVIEW
 16 PROCESS IF APPROVAL OF A CLAIM FOR BENEFITS
 17 DURING PROCESS.—

18 “(A) IN GENERAL.—If a plan or issuer—

19 “(i) reverses a determination on a de-
 20 nial of a claim for benefits that is the sub-
 21 ject of an external review under this sec-
 22 tion and authorizes coverage for the claim
 23 or provides payment of the claim; and

24 “(ii) provides notice of such reversal
 25 to the participant or beneficiary (or au-

thorized representative) and the treating health care professional (if any), and the external review entity responsible for such review,

the external review process shall be terminated with respect to such denial and any filing fee paid under subsection (b)(2)(A)(iv) shall be refunded.

“(B) TREATMENT OF TERMINATION.—An authorization of coverage under subparagraph (A) by the plan or issuer shall be treated as a written determination to reverse a denial under section (d)(3)(F) for purposes of liability under section 502(n)(1)(B).

“(f) COMPLIANCE.—

“(1) APPLICATION OF DETERMINATIONS.—

“(A) EXTERNAL REVIEW DETERMINATIONS BINDING ON PLAN.—The determinations of an external review entity and an independent medical reviewer under this section shall be binding upon the plan or issuer involved.

“(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical reviewer is to reverse the denial, the plan or issuer, upon the receipt of such deter-

1 mination, shall authorize coverage to comply
2 with the medical reviewer's determination in ac-
3 cordance with the timeframe established by the
4 medical reviewer under subsection (d)(3)(F).

5 “(2) FAILURE TO COMPLY.—If a plan or issuer
6 fails to comply with the timeframe established under
7 paragraph (1)(B) with respect to a participant or
8 beneficiary, where such failure to comply is caused
9 by the plan or issuer, the participant or beneficiary
10 may obtain the items or services involved (in a man-
11 ner consistent with the determination of the inde-
12 pendent external reviewer) from any provider re-
13 gardless of whether such provider is a participating
14 provider under the plan or coverage.

15 “(3) REIMBURSEMENT.—

16 “(A) IN GENERAL.—Where a participant
17 or beneficiary obtains items or services in ac-
18 cordance with paragraph (2), the plan or issuer
19 involved shall provide for reimbursement of the
20 costs of such items or services. Such reimburse-
21 ment shall be made to the treating health care
22 professional or to the participant or beneficiary
23 (in the case of a participant or beneficiary who
24 pays for the costs of such items or services).

1 “(B) AMOUNT.—The plan or issuer shall
2 fully reimburse a professional, participant or
3 beneficiary under subparagraph (A) for the
4 total costs of the items or services provided (re-
5 gardless of any plan limitations that may apply
6 to the coverage of such items or services) so
7 long as—

8 “(i) the items or services would have
9 been covered under the terms of the plan
10 or coverage if provided by the plan or
11 issuer; and

12 “(ii) the items or services were pro-
13 vided in a manner consistent with the de-
14 termination of the independent medical re-
15 viewer.

16 “(4) FAILURE TO REIMBURSE.—Where a plan
17 or issuer fails to provide reimbursement to a profes-
18 sional, participant or beneficiary in accordance with
19 this subsection, the professional, participant or bene-
20 ficiary may commence a civil action (or utilize other
21 remedies available under law) to recover only the
22 amount of any such reimbursement that is unpaid
23 and any necessary legal costs or expenses (including
24 attorneys’ fees) incurred in recovering such reim-
25 bursement.

1 “(g) QUALIFICATIONS OF INDEPENDENT MEDICAL
2 REVIEWERS.—

3 “(1) IN GENERAL.—In referring a denial to 1
4 or more individuals to conduct independent medical
5 review under subsection (c), the qualified external
6 review entity shall ensure that—

7 “(A) each independent medical reviewer
8 meets the qualifications described in paragraphs
9 (2) and (3);

10 “(B) with respect to each review at least 1
11 such reviewer meets the requirements described
12 in paragraphs (4) and (5); and

13 “(C) compensation provided by the entity
14 to the reviewer is consistent with paragraph
15 (6).

16 “(2) LICENSURE AND EXPERTISE.—

17 “(A) IN GENERAL.—Subject to subpara-
18 graph (B), each independent medical reviewer
19 shall be a physician (who may be an allopathic
20 or osteopathic physician) or health care profes-
21 sional who—

22 “(i) is appropriately credentialed or li-
23 censed in 1 or more States to deliver
24 health care services; and

1 “(ii) typically treats the diagnosis or
2 condition or provides the type of treatment
3 under review.

4 “(B) PHYSICIAN REVIEW.—In referring a
5 denial for independent medical review under
6 subsection (c), the qualified external review en-
7 tity shall ensure that, in the case of the review
8 of treatment that is recommended or provided
9 by a physician, such referral may be made only
10 to a physician for such independent medical re-
11 view.

12 “(3) INDEPENDENCE.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B), each independent medical reviewer
15 in a case shall—

16 “(i) not be a related party (as defined
17 in paragraph (7));

18 “(ii) not have a material familial, fi-
19 nancial, or professional relationship with
20 such a party; and

21 “(iii) not otherwise have a conflict of
22 interest with such a party (as determined
23 under regulations).

24 “(B) EXCEPTION.—Nothing in this sub-
25 paragraph (A) shall be construed to—

1 “(i) prohibit an individual, solely on
 2 the basis of affiliation with the plan or
 3 issuer, from serving as an independent
 4 medical reviewer if—

5 “(I) a non-affiliated individual is
 6 not reasonably available;

7 “(II) the affiliated individual is
 8 not involved in the provision of items
 9 or services in the case under review;

10 “(III) the fact of such an affili-
 11 ation is disclosed to the plan or issuer
 12 and the participant or beneficiary (or
 13 authorized representative) and neither
 14 party objects; and

15 “(IV) the affiliated individual is
 16 not an employee of the plan or issuer
 17 and does not provide services exclu-
 18 sively or primarily to or on behalf of
 19 the plan or issuer;

20 “(ii) prohibit an individual who has
 21 staff privileges at the institution where the
 22 treatment involved takes place from serv-
 23 ing as an independent medical reviewer if
 24 the affiliation is disclosed to the plan or
 25 issuer and the participant or beneficiary

1 (or authorized representative), and neither
 2 party objects; or

3 “(iii) prohibit receipt of compensation
 4 by an independent medical reviewer from
 5 an entity if the compensation is provided
 6 consistent with paragraph (6).

7 “(4) PRACTICING HEALTH CARE PROFESSIONAL
 8 IN SAME FIELD.—

9 “(A) IN GENERAL.—The requirement of
 10 this paragraph with respect to a reviewer in a
 11 case involving treatment, or the provision of
 12 items or services, by—

13 “(i) a physician, is that the reviewer
 14 be a practicing physician of the same or
 15 similar specialty as a physician who typi-
 16 cally treats the diagnosis or condition or
 17 provides such treatment in the case under
 18 review; or

19 “(ii) a health care professional (other
 20 than a physician), is that the reviewer be
 21 a practicing physician or, if determined ap-
 22 propriate by the qualified external review
 23 entity, a health care professional (other
 24 than a physician), of the same or similar
 25 specialty as the health care professional

1 who typically treats the diagnosis or condi-
 2 tion or provides the treatment in the case
 3 under review.

4 “(B) PRACTICING DEFINED.—For
 5 purposes of this paragraph, the term ‘prac-
 6 ticing’ means, with respect to an individual
 7 who is a physician or other health care
 8 professional that the individual provides
 9 health care services to individual patients
 10 on average at least 1 day per week.

11 “(5) AGE-APPROPRIATE EXPERTISE.—The inde-
 12 pendent medical reviewer shall have expertise under
 13 paragraph (2) that is age-appropriate to the partici-
 14 pant or beneficiary involved.

15 “(6) LIMITATIONS ON REVIEWER COMPENSA-
 16 TION.—Compensation provided by a qualified exter-
 17 nal review entity to an independent medical reviewer
 18 in connection with a review under this section
 19 shall—

20 “(A) not exceed a reasonable level; and

21 “(B) not be contingent on the decision ren-
 22 dered by the reviewer.

23 “(7) RELATED PARTY DEFINED.—For purposes
 24 of this section, the term ‘related party’ means, with
 25 respect to a denial of a claim under a plan or cov-

1 erage relating to a participant or beneficiary, any of
 2 the following:

3 “(A) The plan, plan sponsor, or issuer in-
 4 volved, or any fiduciary, officer, director, or em-
 5 ployee of such plan, plan sponsor, or issuer.

6 “(B) The participant or beneficiary (or au-
 7 thorized representative).

8 “(C) The health care professional that pro-
 9 vides the items of services involved in the de-
 10 nial.

11 “(D) The institution at which the items or
 12 services (or treatment) involved in the denial
 13 are provided.

14 “(E) The manufacturer of any drug or
 15 other item that is included in the items or serv-
 16 ices involved in the denial.

17 “(F) Any other party determined under
 18 any regulations to have a substantial interest in
 19 the denial involved.

20 “(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

21 “(1) SELECTION OF QUALIFIED EXTERNAL RE-
 22 VIEW ENTITIES.—

23 “(A) LIMITATION ON PLAN OR ISSUER SE-
 24 LECTION.—The Secretary shall implement pro-
 25 cedures with respect to the selection of qualified

external review entities by a plan or issuer to assure that the selection process among qualified external review entities will not create any incentives for external review entities to make a decision in a biased manner.

“(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for the designation or selection of qualified external review entities in a manner determined by the State to assure an unbiased determination in conducting external review activities. In conducting reviews under this section, an entity designated or selected under this subparagraph shall comply with provisions of this section.

“(2) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more qualified external review entities (as defined in paragraph (4)(A)).

1 “(3) TERMS AND CONDITIONS OF CONTRACT.—

2 The terms and conditions of a contract under para-
3 graph (2) shall—

4 “(A) be consistent with the standards the
5 Secretary shall establish to assure there is no
6 real or apparent conflict of interest in the con-
7 duct of external review activities; and

8 “(B) provide that the costs of the external
9 review process shall be borne by the plan or
10 issuer.

11 Subparagraph (B) shall not be construed as apply-
12 ing to the imposition of a filing fee under subsection
13 (b)(2)(A)(iv) or costs incurred by the participant or
14 beneficiary (or authorized representative) or treating
15 health care professional (if any) in support of the re-
16 view, including the provision of additional evidence
17 or information.

18 “(4) QUALIFICATIONS.—

19 “(A) IN GENERAL.—In this section, the
20 term ‘qualified external review entity’ means, in
21 relation to a plan or issuer, an entity that is
22 initially certified (and periodically recertified)
23 under subparagraph (C) as meeting the fol-
24 lowing requirements:

1 “(i) The entity has (directly or
2 through contracts or other arrangements)
3 sufficient medical, legal, and other exper-
4 tise and sufficient staffing to carry out du-
5 ties of a qualified external review entity
6 under this section on a timely basis, in-
7 cluding making determinations under sub-
8 section (b)(2)(A) and providing for inde-
9 pendent medical reviews under subsection
10 (d).

11 “(ii) The entity is not a plan or issuer
12 or an affiliate or a subsidiary of a plan or
13 issuer, and is not an affiliate or subsidiary
14 of a professional or trade association of
15 plans or issuers or of health care providers.

16 “(iii) The entity has provided assur-
17 ances that it will conduct external review
18 activities consistent with the applicable re-
19 quirements of this section and standards
20 specified in subparagraph (C), including
21 that it will not conduct any external review
22 activities in a case unless the independence
23 requirements of subparagraph (B) are met
24 with respect to the case.

1 “(iv) The entity has provided assur-
 2 ances that it will provide information in a
 3 timely manner under subparagraph (D).

4 “(v) The entity meets such other re-
 5 quirements as the Secretary provides by
 6 regulation.

7 “(B) INDEPENDENCE REQUIREMENTS.—

8 “(i) IN GENERAL.—Subject to clause
 9 (ii), an entity meets the independence re-
 10 quirements of this subparagraph with re-
 11 spect to any case if the entity—

12 “(I) is not a related party (as de-
 13 fined in subsection (g)(7));

14 “(II) does not have a material fa-
 15 milial, financial, or professional rela-
 16 tionship with such a party; and

17 “(III) does not otherwise have a
 18 conflict of interest with such a party
 19 (as determined under regulations).

20 “(ii) EXCEPTION FOR REASONABLE
 21 COMPENSATION.—Nothing in clause (i)
 22 shall be construed to prohibit receipt by a
 23 qualified external review entity of com-
 24 pensation from a plan or issuer for the
 25 conduct of external review activities under

1 this section if the compensation is provided
 2 consistent with clause (iii).

3 “(iii) LIMITATIONS ON ENTITY COM-
 4 PENSATION.—Compensation provided by a
 5 plan or issuer to a qualified external review
 6 entity in connection with reviews under
 7 this section shall—

8 “(I) not exceed a reasonable
 9 level; and

10 “(II) not be contingent on the
 11 decision rendered by the entity or by
 12 any independent medical reviewer.

13 “(C) CERTIFICATION AND RECERTIFI-
 14 CATION PROCESS.—

15 “(i) IN GENERAL.—The initial certifi-
 16 cation and recertification of a qualified ex-
 17 ternal review entity shall be made—

18 “(I) under a process that is rec-
 19 ognized or approved by the Secretary;
 20 or

21 “(II) by a qualified private
 22 standard-setting organization that is
 23 approved by the Secretary under
 24 clause (iii).

1 “(ii) PROCESS.—The Secretary shall
2 not recognize or approve a process under
3 clause (i)(I) unless the process applies
4 standards (as promulgated in regulations)
5 that ensure that a qualified external review
6 entity—

7 “(I) will carry out (and has car-
8 ried out, in the case of recertification)
9 the responsibilities of such an entity
10 in accordance with this section, in-
11 cluding meeting applicable deadlines;

12 “(II) will meet (and has met, in
13 the case of recertification) appropriate
14 indicators of fiscal integrity;

15 “(III) will maintain (and has
16 maintained, in the case of recertifi-
17 cation) appropriate confidentiality
18 with respect to individually identifi-
19 able health information obtained in
20 the course of conducting external re-
21 view activities; and

22 “(IV) in the case recertification,
23 shall review the matters described in
24 clause (iv).

1 “(iii) APPROVAL OF QUALIFIED PRI-
2 VATE STANDARD-SETTING ORGANIZA-
3 TIONS.—For purposes of clause (i)(II), the
4 Secretary may approve a qualified private
5 standard-setting organization if the Sec-
6 retary finds that the organization only cer-
7 tifies (or recertifies) external review enti-
8 ties that meet at least the standards re-
9 quired for the certification (or recertifi-
10 cation) of external review entities under
11 clause (ii).

12 “(iv) CONSIDERATIONS IN RECERTIFI-
13 CATIONS.—In conducting recertifications of
14 a qualified external review entity under
15 this paragraph, the Secretary or organiza-
16 tion conducting the recertification shall re-
17 view compliance of the entity with the re-
18 quirements for conducting external review
19 activities under this section, including the
20 following:

21 “(I) Provision of information
22 under subparagraph (D).

23 “(II) Adherence to applicable
24 deadlines (both by the entity and by

1 independent medical reviewers it re-
2 fers cases to).

3 “(III) Compliance with limita-
4 tions on compensation (with respect to
5 both the entity and independent med-
6 ical reviewers it refers cases to).

7 “(IV) Compliance with applicable
8 independence requirements.

9 “(v) PERIOD OF CERTIFICATION OR
10 RECERTIFICATION.—A certification or re-
11 certification provided under this paragraph
12 shall extend for a period not to exceed 5
13 years.

14 “(vi) REVOCATION.—A certification or
15 recertification under this paragraph may
16 be revoked by the Secretary or by the or-
17 ganization providing such certification
18 upon a showing of cause.

19 “(D) PROVISION OF INFORMATION.—

20 “(i) IN GENERAL.—A qualified exter-
21 nal review entity shall provide to the Sec-
22 retary, in such manner and at such times
23 as the Secretary may require, such infor-
24 mation (relating to the denials which have
25 been referred to the entity for the conduct

of external review under this section) as the Secretary determines appropriate to assure compliance with the independence and other requirements of this section to monitor and assess the quality of its external review activities and lack of bias in making determinations. Such information shall include information described in clause (ii) but shall not include individually identifiable medical information.

“(ii) INFORMATION TO BE INCLUDED.—The information described in this subclause with respect to an entity is as follows:

“(I) The number and types of denials for which a request for review has been received by the entity.

“(II) The disposition by the entity of such denials, including the number referred to a independent medical reviewer and the reasons for such dispositions (including the application of exclusions), on a plan or issuer-specific basis and on a health care specialty-specific basis.

1 “(III) The length of time in mak-
2 ing determinations with respect to
3 such denials.

4 “(IV) Updated information on
5 the information required to be sub-
6 mitted as a condition of certification
7 with respect to the entity’s perform-
8 ance of external review activities.

9 “(iii) INFORMATION TO BE PROVIDED
10 TO CERTIFYING ORGANIZATION.—

11 “(I) IN GENERAL.—In the case
12 of a qualified external review entity
13 which is certified (or recertified)
14 under this subsection by a qualified
15 private standard-setting organization,
16 at the request of the organization, the
17 entity shall provide the organization
18 with the information provided to the
19 Secretary under clause (i).

20 “(II) ADDITIONAL INFORMA-
21 TION.—Nothing in this subparagraph
22 shall be construed as preventing such
23 an organization from requiring addi-
24 tional information as a condition of

1 certification or recertification of an
2 entity.

3 “(iv) USE OF INFORMATION.—

4 “(I) IN GENERAL.—Information
5 provided under this subparagraph
6 may be used by the Secretary and
7 qualified private standard-setting or-
8 ganizations to conduct oversight of
9 qualified external review entities, in-
10 cluding recertification of such entities,
11 and shall be made available to the
12 public in an appropriate manner.

13 “(II) REPORT TO CONGRESS.—
14 Not later than 2 years after the date
15 on which the Bipartisan Patients’ Bill
16 of Rights Act of 2001 takes effect
17 under section 501 of such Act, and
18 every 2 years thereafter, the Sec-
19 retary, in consultation with the Sec-
20 retary of Health and Human Services,
21 shall prepare and submit to the ap-
22 propriate committees of Congress, a
23 report that contains—

1 “(aa) a summary of the in-
2 formation provided to the Sec-
3 retary under clause (ii);

4 “(bb) a description of the ef-
5 fect that the appeals process es-
6 tablished under this section and
7 section 503A had on the access
8 of individuals to health insurance
9 and health care;

10 “(cc) a description of the ef-
11 fect on health care costs associ-
12 ated with the implementation of
13 the appeals process described in
14 item (bb); and

15 “(dd) a description of the
16 quality and consistency of deter-
17 minations by qualified external
18 review entities.

19 “(III) RECOMMENDATIONS.—The
20 Secretary may from time to time sub-
21 mit recommendations to Congress
22 with respect to proposed modifications
23 to the appeals process based on the
24 reports submitted under subclause
25 (II).

1 “(E) LIMITATION ON LIABILITY.—No
 2 qualified external review entity having a con-
 3 tract with a plan or issuer, and no person who
 4 is employed by any such entity or who furnishes
 5 professional services to such entity (including as
 6 an independent medical reviewer), shall be held
 7 by reason of the performance of any duty, func-
 8 tion, or activity required or authorized pursuant
 9 to this section, to be civilly liable under any law
 10 of the United States or of any State (or polit-
 11 ical subdivision thereof) if there was no actual
 12 malice or gross misconduct in the performance
 13 of such duty, function, or activity.

14 “(i) DEFINITIONS.—In this section:

15 “(1) AUTHORIZED REPRESENTATIVE.—The
 16 term ‘authorized representative’ means, with respect
 17 to a participant or beneficiary—

18 “(A) a person to whom a participant or
 19 beneficiary has given express written consent to
 20 represent the participant or beneficiary in any
 21 proceeding under this section;

22 “(B) a person authorized by law to provide
 23 substituted consent for the participant or bene-
 24 ficiary; or

1 “(C) a family member of the participant or
2 beneficiary (or the estate of the participant or
3 beneficiary) or the participant’s or beneficiary’s
4 treating health care professional when the par-
5 ticipant or beneficiary is unable to provide con-
6 sent.

7 “(2) CLAIM FOR BENEFITS.—The term ‘claim
8 for benefits’ means any request by a participant or
9 beneficiary (or authorized representative) for bene-
10 fits (including requests that are subject to authoriza-
11 tion of coverage or utilization review), for eligibility,
12 or for payment in whole or in part, for an item or
13 service under a group health plan or health insur-
14 ance coverage offered by a health insurance issuer in
15 connection with a group health plan.

16 “(3) GROUP HEALTH PLAN.—The term ‘group
17 health plan’ shall have the meaning given such term
18 in section 733(a). In applying this paragraph, ex-
19 cepted benefits described in section 733(c) shall not
20 be treated as benefits consisting of medical care.

21 “(4) HEALTH INSURANCE COVERAGE.—The
22 term ‘health insurance coverage’ has the meaning
23 given such term in section 733(b)(1). In applying
24 this paragraph, excepted benefits described in sec-

1 tion 733(c) shall not be treated as benefits con-
2 sisting of medical care.

3 “(5) HEALTH INSURANCE ISSUER.—The term
4 ‘health insurance issuer’ has the meaning given such
5 term in section 733(b)(2).

6 “(6) PRIOR AUTHORIZATION DETERMINA-
7 TION.—The term ‘prior authorization determination’
8 means a determination by the group health plan or
9 health insurance issuer offering health insurance
10 coverage in connection with a group health plan
11 prior to the provision of the items and services as
12 a condition of coverage of the items and services
13 under the terms and conditions of the plan or cov-
14 erage.

15 “(7) TREATING HEALTH CARE PROFES-
16 SIONAL.—The term ‘treating health care profes-
17 sional’ with respect to a group health plan, health
18 insurance issuer or provider sponsored organization
19 means a physician (medical doctor or doctor of oste-
20 opathy) or other health care practitioner who is act-
21 ing within the scope of his or her State licensure or
22 certification for the delivery of health care services
23 and who is primarily responsible for delivering those
24 services to the participant or beneficiary.

1 “(8) UTILIZATION REVIEW.—The term ‘utiliza-
 2 tion review’ with respect to a group health plan or
 3 health insurance coverage means procedures used in
 4 the determination of coverage for a participant or
 5 beneficiary, such as procedures to evaluate the med-
 6 ical necessity, appropriateness, efficacy, quality, or
 7 efficiency of health care services, procedures or set-
 8 tings, and includes prospective review, concurrent re-
 9 view, second opinions, case management, discharge
 10 planning, or retrospective review.”.

11 (b) CONFORMING AMENDMENT.—The table of con-
 12 tents in section 1 of the Employee Retirement Income Se-
 13 curity Act of 1974 is amended by inserting after the item
 14 relating to section 503 the following:

“Sec. 503A. Claims and internal appeals procedures for group health plans.
 “Sec. 503B. Independent external appeals procedures for group health plans.”.

15 **SEC. 132. ENFORCEMENT.**

16 Section 502(c) of the Employee Retirement Income
 17 Security Act of 1974 (29 U.S.C. 1132(c)) is amended by
 18 adding at the end the following:

19 “(8) The Secretary may assess a civil penalty against
 20 any plan of up to \$10,000 for the plan’s failure or refusal
 21 to comply with any deadline applicable under section 503B
 22 or any determination under such section, except that in
 23 any case in which coverage was not approved by the plan
 24 in accordance with the determination of an independent

1 external reviewer, the Secretary shall assess a civil penalty
 2 of \$10,000 against the plan and the plan shall pay such
 3 penalty to the participant or beneficiary involved.”.

4 **Subtitle D—Remedies**

5 **SEC. 141. AVAILABILITY OF COURT REMEDIES.**

6 (a) IN GENERAL.—Section 502 of the Employee Re-
 7 tirement Income Security Act of 1974 (29 U.S.C. 1132)
 8 is amended by adding at the end the following:

9 “(n) CAUSE OF ACTION RELATING TO DENIAL OF A
 10 CLAIM FOR HEALTH BENEFITS.—

11 “(1) IN GENERAL.—

12 “(A) FAILURE TO COMPLY WITH EXTER-
 13 NAL MEDICAL REVIEW.—With respect to an ac-
 14 tion commenced by a participant or beneficiary
 15 (or the estate of the participant or beneficiary)
 16 in connection with a claim for benefits under a
 17 group health plan, if—

18 “(i) a designated decision-maker de-
 19 scribed in paragraph (2) fails to exercise
 20 ordinary care in approving coverage pursu-
 21 ant to the written determination of an
 22 independent medical reviewer under section
 23 503B(d)(3)(F) that reverses a denial of
 24 the claim for benefits; and

1 “(ii) the failure described in clause (i)
 2 is the proximate cause of substantial harm
 3 (as defined in paragraph (10)(G)) to the
 4 participant or beneficiary;
 5 such designated decision-maker shall be liable
 6 to the participant or beneficiary (or the estate)
 7 for economic and noneconomic damages in con-
 8 nection with such failure and such injury or
 9 death (subject to paragraph (4)).

10 “(B) WRONGFUL DETERMINATION RE-
 11 SULTING IN DELAY IN PROVIDING BENEFITS.—
 12 With respect to an action commenced by a par-
 13 ticipant or beneficiary (or the estate of the par-
 14 ticipant or beneficiary) in connection with a
 15 claim for benefits under a group health plan,
 16 if—

17 “(i) a designated decision-maker de-
 18 scribed in paragraph (2)—

19 “(I) fails to exercise ordinary
 20 care in making a determination deny-
 21 ing the claim for benefits under sec-
 22 tion 503A(a) (relating to an initial
 23 claim for benefits); or

24 “(II) fails to exercise ordinary
 25 care in making a determination deny-

1 ing the claim for benefits under sec-
2 tion 503A(b) (relating to an internal
3 appeal);

4 “(ii) the denial described in clause (i)
5 is reversed by an independent medical re-
6 viewer under section 503B(d) or
7 503B(e)(4)(B); and

8 “(iii) the delay attributable to the fail-
9 ure described in clause (i) is the proximate
10 cause of substantial harm to, or the wrong-
11 ful death of, the participant or beneficiary;
12 such designated decision-maker shall be liable
13 to the participant or beneficiary (or the estate)
14 for economic and noneconomic damages in con-
15 nection with such failure and such injury or
16 death (subject to paragraph (4)).

17 “(C) LIMITATION ON LIABILITY BASED ON
18 APPOINTMENT OF DESIGNATED DECISION-
19 MAKER.—If a plan sponsor or named fiduciary
20 appoints a designated decision-maker in accord-
21 ance with paragraph (2), the plan sponsor or
22 named fiduciary, or any other person or group
23 health plan (or their employees) associated with
24 the plan sponsor or named fiduciary, shall not
25 be liable under this paragraph. The appoint-

1 ment of a designated decision-maker in accord-
 2 ance with paragraph (2) shall not affect the li-
 3 ability of the appointing plan sponsor or named
 4 fiduciary for the failure of the plan sponsor or
 5 named fiduciary to comply with any other re-
 6 quirement of this title.

7 “(2) DESIGNATED DECISION-MAKER.—

8 “(A) APPOINTMENT.—

9 “(i) IN GENERAL.—The plan sponsor
 10 or named fiduciary of a group health plan
 11 shall, in accordance with this paragraph,
 12 designate one or more persons to serve as
 13 a designated decision-maker with respect
 14 to causes of action described in subpara-
 15 graphs (A) and (B) of paragraph (1), ex-
 16 cept that—

17 “(I) with respect to health insur-
 18 ance coverage offered in connection
 19 with a group health plan, the health
 20 insurance issuer shall be the des-
 21 ignated decision-maker unless the
 22 plan sponsor and the issuer specifi-
 23 cally agree in writing (on a form to be
 24 prescribed by the Secretary) to sub-

1 stitute another person as the des-
2 ignated decision-maker; or

3 “(II) with respect to the designa-
4 tion of a person other than a plan
5 sponsor or health insurance issuer,
6 such person shall satisfy the require-
7 ments of subparagraph (D).

8 “(ii) PLAN DOCUMENTS.—The des-
9 ignated decision-maker shall be specifically
10 designated as such in the written instru-
11 ments of the plan (under section 402(a))
12 and be identified as required under section
13 121(b)(14) of the Bipartisan Patients’ Bill
14 of Rights Act of 2001.

15 “(B) AUTHORITY.—A designated decision-
16 maker appointed under subparagraph (A) shall
17 have the exclusive authority under the group
18 health plan—

19 “(i) to make determinations with re-
20 spect to a claim for benefits under section
21 503A(a) (relating to an initial claim for
22 benefits);

23 “(ii) to make final determinations
24 under section 503A(b) (relating to an in-
25 ternal appeal); or

1 “(iii) to approve coverage pursuant to
2 the written determination of independent
3 medical reviewers under section 503B.

4 “(C) ALLOCATION OF RESPONSIBILITY.—
5 Responsibility may be allocated among different
6 designated decision-makers with respect to—

7 “(i) for purposes of paragraph (1)(A),
8 the approval of coverage under section
9 503B;

10 “(ii) for purposes of paragraph
11 (1)(B), making determinations on a claim
12 for benefits under section 503A(a) (relat-
13 ing to an initial claim for benefits); and

14 “(iii) for purposes of paragraph
15 (1)(B), making final determinations on
16 claims for benefits under section 503A(b)
17 (relating to internal appeals).

18 Where such an allocation is made, liability
19 under a cause of action under paragraph (1)
20 shall be assessed against the appropriate des-
21 ignated decision-maker.

22 “(D) QUALIFICATIONS.—

23 “(i) CERTIFICATION OF ABILITY.—To
24 be appointed as a designated decision-
25 maker under this paragraph, a person shall

1 provide to the plan sponsor or named fidu-
2 ciary a certification of such person's ability
3 to meet the requirements of clause (ii) re-
4 lating to financial obligation for liability
5 under this subsection. Such certification
6 shall be provided upon appointment and
7 not less frequently than annually there-
8 after, or if the designation is pursuant to
9 a multi-year contract, in conjunction with
10 the renewal of the contract, but in no case
11 less than once every 3 years.

12 “(ii) OTHER REQUIREMENTS RELAT-
13 ING TO FINANCIAL OBLIGATIONS.—For
14 purposes of clause (i), requirements relat-
15 ing to financial obligation for liability shall
16 include evidence of—

17 “(I) coverage of the person under
18 insurance policies or other arrange-
19 ments, secured and maintained by the
20 person, to insure the person against
21 losses arising from professional liabil-
22 ity claims, including those arising
23 from being designated as a designated
24 decision-maker under this paragraph;
25 or

1 “(II) minimum capital and sur-
 2 plus levels that are maintained by the
 3 person to cover any losses as a result
 4 of liability arising from being des-
 5 ignated as a designated decision-
 6 maker under this paragraph.

7 The appropriate amounts of liability insur-
 8 ance and minimum capital and surplus lev-
 9 els for purposes of subclauses (I) and (II)
 10 shall be determined by an actuary using
 11 sound actuarial principles and accounting
 12 practices pursuant to established guidelines
 13 of the American Academy of Actuaries and
 14 shall be maintained throughout the course
 15 of the contract in which such person is
 16 designated as a designated decision-maker.

17 “(E) FLEXIBILITY IN ADMINISTRATION.—
 18 A group health plan, or health insurance issuer
 19 offering health insurance coverage in connection
 20 with a group health plan, may provide—

21 “(i) that any person or group of per-
 22 sons may serve in more than one capacity
 23 with respect to the plan or coverage (in-
 24 cluding service as a designated decision-

1 maker, administrator, and named fidu-
 2 ciary); or

3 “(ii) that a designated decision-maker
 4 may employ one or more persons to pro-
 5 vide advice with respect to any responsi-
 6 bility of such decision-maker under the
 7 plan or coverage.

8 “(F) FAILURE TO APPOINT.—

9 “(i) IN GENERAL.—With respect to
 10 any cause of action under paragraph (1)
 11 relating to a denial of a claim for benefits
 12 where a designated decision-maker has not
 13 been appointed in accordance with this
 14 paragraph, the plan sponsor or named fi-
 15 duciary responsible for determinations
 16 under section 503 shall be deemed to be
 17 the designated decision-maker.

18 “(ii) LIMITATION ON APPOINT-
 19 MENT.—A treating health care professional
 20 who directly delivered the care, treatment,
 21 or provided the patient service that is the
 22 subject of an action under this subsection
 23 may not be designated as a designated de-
 24 cision-maker under this paragraph unless
 25 the professional—

1 “(I) is a person or entity that
 2 may be appointed in accordance with
 3 subparagraph (A); and

4 “(II) specifically agrees to accept
 5 such appointment in accordance with
 6 the requirements under such subpara-
 7 graph.

8 “(3) REQUIREMENT OF EXHAUSTION OF INDE-
 9 PENDENT MEDICAL REVIEW.—

10 “(A) IN GENERAL.—Paragraph (1) shall
 11 apply only if a final determination denying a
 12 claim for benefits under section 503A(b) has
 13 been referred for independent medical review
 14 under section 503B(d) and a written determina-
 15 tion by an independent medical reviewer to re-
 16 verse such final determination has been issued
 17 with respect to such review.

18 “(B) INJUNCTIVE RELIEF FOR IRREP-
 19 ARABLE HARM.—A participant or beneficiary
 20 may seek relief under subsection 502(a)(1)(B)
 21 prior to the exhaustion of administrative rem-
 22 edies under section 503A(b) or 503B (as re-
 23 quired under subparagraph (A)) if it is dem-
 24 onstrated to the court, by a preponderance of
 25 the evidence, that the exhaustion of such rem-

edies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503A or 503B in such case, or that are made in such case while an action under this subparagraph is pending, shall be given due consideration by the court in any action under this subsection in such case. Notwithstanding the awarding of relief under subsection 502(a)(1)(B) pursuant to this subparagraph, no relief shall be available under—

“(i) paragraph (1), with respect to a participant or beneficiary, unless the requirements of subparagraph (A) are met; or

“(ii) subsection (q) unless the requirements of such subsection are met.

“(4) LIMITATIONS ON RECOVERY OF DAMAGES.—

“(A) MAXIMUM AWARD OF NONECONOMIC DAMAGES.—The aggregate amount of liability for noneconomic loss in an action under paragraph (1) may not exceed \$500,000.

“(B) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A) shall be in-

1 creased or decreased, for each calendar year
 2 that ends after December 31, 2002, by the
 3 same percentage as the percentage by which the
 4 Consumer Price Index for All Urban Con-
 5 sumers (United States city average), published
 6 by the Bureau of Labor Statistics, for Sep-
 7 tember of the preceding calendar year has in-
 8 creased or decreased from the such Index for
 9 September of 2002.

10 “(C) SEVERAL LIABILITY.—In the case of
 11 any action commenced pursuant to paragraph
 12 (1), the designated decision-maker shall be lia-
 13 ble only for the amount of noneconomic dam-
 14 ages attributable to such designated decision-
 15 maker in direct proportion to such decision-
 16 maker’s share of fault or responsibility for the
 17 injury suffered by the participant or bene-
 18 ficiary. In all such cases, the liability of a des-
 19 ignated decision-maker for noneconomic dam-
 20 ages shall be several and not joint.

21 “(D) TREATMENT OF COLLATERAL
 22 SOURCE PAYMENTS.—

23 “(i) IN GENERAL.—In the case of any
 24 action commenced pursuant to paragraph
 25 (1), the total amount of damages received

1 by a participant or beneficiary under such
2 action shall be reduced, in accordance with
3 clause (ii), by any other payment that has
4 been, or will be, made to such participant
5 or beneficiary, pursuant to an order or
6 judgment of another court, to compensate
7 such participant or beneficiary for the in-
8 jury that was the subject of such action.

9 “(ii) AMOUNT OF REDUCTION.—The
10 amount by which an award of damages to
11 a participant or beneficiary for an injury
12 shall be reduced under clause (i) shall be—

13 “(I) the total amount of any pay-
14 ments (other than such award) that
15 have been made or that will be made
16 to such participant or beneficiary to
17 pay costs of or compensate such par-
18 ticipant or beneficiary for the injury
19 that was the subject of the action; less

20 “(II) the amount paid by such
21 participant or beneficiary (or by the
22 spouse, parent, or legal guardian of
23 such participant or beneficiary) to se-
24 cure the payments described in sub-
25 clause (I).

1 “(iii) DETERMINATION OF AMOUNTS
 2 FROM COLLATERAL SOURCES.—The reduc-
 3 tion required under clause (ii) shall be de-
 4 termined by the court in a pretrial pro-
 5 ceeding. At the subsequent trial no evi-
 6 dence shall be admitted as to the amount
 7 of any charge, payments, or damage for
 8 which a participant or beneficiary—

9 “(I) has received payment from a
 10 collateral source or the obligation for
 11 which has been assured by a third
 12 party; or

13 “(II) is, or with reasonable cer-
 14 tainty, will be eligible to receive from
 15 a collateral source which will, with
 16 reasonable certainty, be assumed by a
 17 third party.

18 “(E) PROHIBITION OF AWARD OF PUNI-
 19 TIVE DAMAGES.—Notwithstanding any other
 20 provision of law, in the case of any action com-
 21 menced pursuant to paragraph (1), the court
 22 may not award any punitive, exemplary, or
 23 similar damages against a defendant.

1 “(5) AFFIRMATIVE DEFENSES.—In the case of
2 any cause of action under paragraph (1), it shall be
3 an affirmative defense that—

4 “(A) the designated decision-maker of a
5 group health plan, or health insurance issuer
6 that offers health insurance coverage in connec-
7 tion with a group health plan, involved did not
8 receive from the participant or beneficiary (or
9 authorized representative) or the treating health
10 care professional (if any), the information re-
11 quested by the plan or issuer regarding the
12 medical condition of the participant or bene-
13 ficiary that was necessary to make a determina-
14 tion on a claim for benefits under section
15 503A(a) or a final determination on a claim for
16 benefits under section 503A(b);

17 “(B) the participant or beneficiary (or au-
18 thorized representative)—

19 “(i) was in possession of facts that
20 were sufficient to enable the participant or
21 beneficiary (or authorized representative)
22 to know that an expedited review under
23 section 503A or 503B would have pre-
24 vented the harm that is the subject of the
25 action; and

1 “(ii) failed to notify the plan or issuer
 2 of the need for such an expedited review;
 3 or

4 “(C) the qualified external review entity or
 5 an independent medical reviewer failed to meet
 6 the timelines applicable under section 503B, or
 7 a period of time elapsing after coverage has
 8 been authorized.

9 Nothing in this paragraph shall be construed to limit
 10 the application of any other affirmative defense that
 11 may be applicable to the cause of action involved.

12 “(6) WAIVER OF INTERNAL REVIEW.—In the
 13 case of any cause of action under paragraph (1), the
 14 waiver or nonwaiver of internal review under section
 15 503A(b)(1)(D) by the group health plan, or health
 16 insurance issuer that offers health insurance cov-
 17 erage in connection with a group health plan, shall
 18 not be used in determining liability.

19 “(7) LIMITATIONS ON ACTIONS.—Paragraph
 20 (1) shall not apply in connection with any action
 21 that is commenced more than 3 years after the date
 22 on which the failure described in paragraph (1) oc-
 23 curred.

24 “(8) PROTECTION OF THE REGULATION OF
 25 QUALITY OF MEDICAL CARE UNDER STATE LAW.—

1 Nothing in this subsection shall be construed to pre-
 2 clude any action under State law against a person
 3 or entity for liability or vicarious liability with re-
 4 spect to the delivery of medical care. A claim that
 5 is based on or otherwise relates to a group health
 6 plan’s administration or determination of a claim for
 7 benefits (as such term is defined in section
 8 503B(i)(2) and notwithstanding the definition con-
 9 tained in paragraph (10)(B)) shall not be deemed to
 10 be the delivery of medical care under any State law
 11 for purposes of this section. Any such claim shall be
 12 maintained exclusively under section 502.

13 “(9) CONSTRUCTION.—Nothing in this sub-
 14 section shall be construed as authorizing a cause of
 15 action under paragraph (1) for the failure of a
 16 group health plan or health insurance issuer to pro-
 17 vide an item or service that is specifically excluded
 18 under the plan or coverage.

19 “(10) DEFINITIONS.—In this subsection:

20 “(A) AUTHORIZED REPRESENTATIVE.—
 21 The term ‘authorized representative’ has the
 22 meaning given such term in section 503B(i).

23 “(B) CLAIM FOR BENEFITS.—Except as
 24 provided for in paragraph (8), the term ‘claim
 25 for benefits’ shall have the meaning given such

1 term in section 503B(i), except that such term
2 shall only include claims for prior authorization
3 determinations (as such term is defined in sec-
4 tion 503B(i)).

5 “(C) GROUP HEALTH PLAN.—The term
6 ‘group health plan’ shall have the meaning
7 given such term in section 733(a). In applying
8 this paragraph, excepted benefits described in
9 section 733(c) shall not be treated as benefits
10 consisting of medical care.

11 “(D) HEALTH INSURANCE COVERAGE.—
12 The term ‘health insurance coverage’ has the
13 meaning given such term in section 733(b)(1).
14 In applying this paragraph, excepted benefits
15 described in section 733(c) shall not be treated
16 as benefits consisting of medical care.

17 “(E) HEALTH INSURANCE ISSUER.—The
18 term ‘health insurance issuer’ has the meaning
19 given such term in section 733(b)(2).

20 “(F) ORDINARY CARE.—The term ‘ordi-
21 nary care’ means the care, skill, prudence, and
22 diligence under the circumstances then pre-
23 vailing that a prudent individual acting in a like
24 capacity and familiar with such matters would

1 use in making a determination on a claim for
 2 benefits of a similar character.

3 “(G) SUBSTANTIAL HARM.—The term
 4 ‘substantial harm’ means the loss of life, loss or
 5 significant impairment of limb or bodily func-
 6 tion, significant mental illness or disease, sig-
 7 nificant disfigurement, or severe and chronic
 8 physical pain.

9 “(11) EFFECTIVE DATE.—The provisions of
 10 this subsection shall apply to acts and omissions oc-
 11 ccurring on or after the effective date of sections
 12 503A and 503B (as contained in section 501 of the
 13 Bipartisan Patients’ Bill of Rights Act of 2001).”.

14 (b) CONFORMING AMENDMENT.—Section
 15 502(a)(1)(A) of the Employee Retirement Income Security
 16 Act of 1974 (29 U.S.C. 1132(a)(1)(A)) is amended by in-
 17 serting “or (n)” after “subsection (c)”.

18 **SEC. 142. LIMITATION ON CERTAIN CLASS ACTION LITIGA-**
 19 **TION.**

20 (a) ERISA.—Section 502 of the Employee Retire-
 21 ment Income Security Act of 1974 (29 U.S.C. 1132), as
 22 amended by section 131, is further amended by adding
 23 at the end the following:

24 “(p) LIMITATION ON CLASS ACTION LITIGATION.—

1 “(1) IN GENERAL.—Any claim or cause of ac-
2 tion that is maintained under this section in connec-
3 tion with a group health plan, or health insurance
4 coverage issued in connection with a group health
5 plan, as a class action, derivative action, or as an ac-
6 tion on behalf of any group of 2 or more claimants,
7 may be maintained only if the class, the derivative
8 claimant, or the group of claimants is limited to the
9 participants or beneficiaries of a group health plan
10 established by only 1 plan sponsor. No action main-
11 tained by such class, such derivative claimant, or
12 such group of claimants may be joined in the same
13 proceeding with any action maintained by another
14 class, derivative claimant, or group of claimants or
15 consolidated for any purpose with any other pro-
16 ceeding. In this paragraph, the terms ‘group health
17 plan’ and ‘health insurance coverage’ have the mean-
18 ings given such terms in section 733.”.

19 “(2) EFFECTIVE DATE.—This subsection shall
20 apply to all civil actions that are filed on or after the
21 date of enactment of the Bipartisan Patients’ Bill of
22 Rights Act of 2001. This subsection shall apply to
23 civil actions that are pending and have not been fi-
24 nally determined by judgment or settlement prior to
25 such date of enactment.”.

1 (b) RICO.—Section 1964(c) of title 18, United
2 States Code, is amended—

3 (1) by inserting “(1)” after the subsection des-
4 ignation; and

5 (2) by adding at the end the following:

6 “(2)(A) No action may be brought under this sub-
7 section, or alleging any violation of section 1962, where
8 the action seeks relief concerning the manner in which any
9 person has marketed, provided information concerning, es-
10 tablished, administered, or otherwise operated a group
11 health plan, or health insurance coverage in connection
12 with a group health plan. Any such action shall only be
13 brought under the Employee Retirement Income Security
14 Act of 1974. In this paragraph, the terms ‘group health
15 plan’ and ‘health insurance issuer’ shall have the meanings
16 given such terms in section 733 of the Employee Retire-
17 ment Income Security Act of 1974.

18 “(B) Subparagraph (A) shall apply to civil actions
19 that are pending and have not been finally determined by
20 judgment or settlement prior to the date of enactment of
21 the Bipartisan Patients’ Bill of Rights Act of 2001 and
22 all actions commenced on or after such date.”.

1 **SEC. 143. AUTHORITY TO IMPOSE CIVIL PENALTIES FOR**
 2 **FAILURE TO PROVIDE A PLAN BENEFIT NOT**
 3 **ELIGIBLE FOR MEDICAL REVIEW.**

4 Section 502 of the Employee Retirement Income Se-
 5 curity Act of 1974 (29 U.S.C. 1132), as amended by sec-
 6 tions 131 and 141, is further amended by adding at the
 7 end the following:

8 “(q) In connection with any action maintained under
 9 subsection (a)(1)(B), the court, in its discretion, may as-
 10 sess a civil penalty against the designated decision-maker
 11 (as designated pursuant to section 502(n)(2)) of a group
 12 health plan or a health insurance issuer (that offers health
 13 insurance coverage in connection with a group health
 14 plan) of not to exceed \$100,000 where—

15 “(1) in its final determination under section
 16 503A(b)(4)(B), the designated decision-maker fails
 17 to provide, or authorize coverage of, a benefit to
 18 which a participant or beneficiary is entitled under
 19 the terms and conditions of the plan;

20 “(2) the participant or beneficiary has appealed
 21 such determination under section 503B and such de-
 22 termination is not subject to independent medical re-
 23 view as determined by a qualified external review en-
 24 tity under section 503B(c)(3)(A);

25 “(3) the plan has failed to exercise ordinary
 26 care in making a final determination under section

1 503A(b)(4)(B) denying a claim for benefits under
2 the plan; and

3 “(4) that denial is the proximate cause of sub-
4 stantial harm (as defined in subsection (n)(10)(G))
5 the participant or beneficiary.”.

6 **Subtitle E—State Flexibility**

7 **SEC. 151. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-** 8 **TION.**

9 (a) LIMITATION ON PREEMPTION OF STATE LAW
10 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

11 (1) IN GENERAL.—Subject to paragraph (2)—

12 (A) subtitles A and B of shall not be con-
13 strued to supersede any provision of State law
14 which establishes, implements, or continues in
15 effect any standard or requirement solely relat-
16 ing to health insurance issuers (in connection
17 with group health plans or individual health in-
18 surance coverage) and to non-Federal govern-
19 mental plans except to the extent that such
20 standard or requirement prevents the applica-
21 tion of a requirement of such subtitles; and

22 (B) the amendments made by subtitle C
23 shall not be construed to supersede any provi-
24 sion of State law which establishes, implements,
25 or continues in effect any standard or require-

ment solely relating to health insurance issuers in connection with individual health insurance coverage and to non-Federal governmental plans except to the extent that such standard or requirement prevents the application of a requirement of such amendments.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) with respect to group health plans.

(b) CONTINUED APPLICATION OF CERTAIN STATE LAWS.—

(1) REQUIREMENTS FOR CONTINUED APPLICATION.—

(A) GENERAL RULE.—With respect to a State law described in subparagraph (B), in applying the requirements of subtitles A and B to health insurance issuers under sections 2707 and 2753 (as applicable) of the Public Health Service Act (as added by title II), or health insurance issuers in connection with group health plans under section 714 of the Employee Retirement Income Security Act of 1974 (as

added by title III), subject to subsection
(a)(2)—

(i) the State law shall not be treated
as being superseded under subsection (a);
and

(ii) the State law shall apply in lieu of
the patient protection requirements other-
wise applicable under such subtitles with
respect to health insurance issuers (in con-
nection with group health plans or indi-
vidual health insurance coverage) and non-
Federal governmental plans.

(B) STATE LAW DESCRIBED.—A State law
described in this subparagraph is a State law
that imposes, with respect to health insurance
issuers (in connection with group health plans
or individual health insurance coverage) and to
non-Federal governmental plans, a requirement
that is approved by the Secretary (through a
certification under subsection (c)(4)) as being
consistent with a patient protection requirement
(as defined in paragraph (3)).

(2) LIMITATION.—In the case of a group health
plan covered under title I of the Employee Retire-
ment Income Security Act of 1974, paragraph (1)

1 shall be construed to apply only with respect to the
2 health insurance coverage (if any) offered in connec-
3 tion with the plan.

4 (3) PATIENT PROTECTION REQUIREMENT DE-
5 FINED.—For purposes of this section, the term “pa-
6 tient protection requirement” means any one or
7 more requirements under the following:

8 (A) Section 101 (relating to access to
9 emergency care).

10 (B) Section 102 (relating to consumer
11 choice option) with respect to non-Federal gov-
12 ernmental plans only.

13 (C) Section 103 (relating to patient access
14 to obstetrical and gynecological care).

15 (D) Section 104 (relating to access to pedi-
16 atric care).

17 (E) Section 105 (relating to timely access
18 to specialists).

19 (F) Section 106 (relating to continuity of
20 care), but only insofar as a replacement issuer
21 assumes the obligation for continuity of care.

22 (G) Section 108 (relating to access to
23 needed prescription drugs).

1 (H) Section 109 (relating to coverage for
2 individuals participating in approved clinical
3 trials).

4 (I) Section 110 (relating to required cov-
5 erage for minimum hospital stay for
6 mastectomies and lymph node dissections for
7 the treatment of breast cancer and coverage for
8 secondary consultations).

9 (J) A prohibition under—

10 (i) section 107 (relating to prohibition
11 of interference with certain medical com-
12 munications); and

13 (ii) section 111 (relating to prohibi-
14 tion of discrimination against providers
15 based on licensure).

16 (K) An informational requirement under
17 section 121.

18 (c) DETERMINATIONS WITH RESPECT TO CERTIFI-
19 CATIONS.—

20 (1) IN GENERAL.—For purposes of the contin-
21 ued application of certain State laws under sub-
22 section (b)(1), a State may, on or after May 1,
23 2002, submit to the Board established under sub-
24 section (d) a certification that the State law involved
25 is consistent with those patient protections require-

1 ments (as defined in subsection (b)(3)) that are cov-
2 ered under the law for which the State is seeking a
3 certification. Such certification shall be accompanied
4 by such information as may be required to permit
5 the Board to make the determination described in
6 paragraph (3), as applicable.

7 (2) ACTION BY BOARD.—

8 (A) IN GENERAL.—The Board shall
9 promptly review a certification submitted under
10 paragraph (1) with respect to a State law to
11 make the determination required under para-
12 graph (3) with respect to the certification.

13 (B) APPROVAL DEADLINES.—

14 (i) INITIAL REVIEW.—Not later than
15 60 days after the date on which the Board
16 receives a certification under paragraph
17 (1), the Board shall—

18 (I) notify the State involved that
19 specified additional information is
20 needed to make the determination de-
21 scribed in paragraph (3); or

22 (II) submit a recommendation to
23 the Secretary concerning the approval
24 or disapproval (and the reasons there-
25 fore) of the certification.

1 (ii) ADDITIONAL INFORMATION.—

2 With respect to a State that has been noti-
 3 fied by the Board under clause (i)(I) that
 4 specified additional information is needed
 5 to make the determination described in
 6 paragraph (3), the Board shall make the
 7 submission required under clause (i)(II)
 8 within 60 days after the date on which
 9 such specified additional information is re-
 10 quested by the Board.

11 (3) DETERMINATION.—The Board shall rec-
 12 ommend that the Secretary approve or disapprove a
 13 certification submitted under paragraph (1)(A). The
 14 Board shall recommend the approval of a certifi-
 15 cation under this subparagraph unless the Board
 16 finds that there is no reasonable basis or evidence
 17 for such approval.

18 (4) REVIEW BY SECRETARY.—

19 (A) IN GENERAL.—The recommendation
 20 by the Board to approve or disapprove a certifi-
 21 cation submitted by a State under paragraph
 22 (1) is considered to be approved by the Sec-
 23 retary unless the Secretary notifies the State in
 24 writing, within 30 days after the date on which
 25 the Board submits its recommendation to the

1 Secretary under paragraph (2) concerning such
2 certification, that the certification is approved
3 or disapproved (and the reasons for the ap-
4 proval or disapproval).

5 (B) DEFERENCE TO STATES.—The rec-
6 ommendation of the Board to approve a certifi-
7 cation submitted under paragraph (1) shall be
8 approved by the Secretary unless the Secretary
9 finds that there is no reasonable basis or there
10 is insufficient evidence for approving the certifi-
11 cation.

12 (C) NOTICE.—

13 (i) STATE NOTIFICATION.—The Sec-
14 retary shall provide a State with written
15 notice of the determination of the Sec-
16 retary to approve or disapprove the certifi-
17 cation submitted by the State under para-
18 graph (1) within 30 days after the date on
19 which the Board submits its recommenda-
20 tion to the Secretary under paragraph (2)
21 concerning such certification.

22 (ii) PUBLIC NOTIFICATION.—The Sec-
23 retary shall publish each notice provided
24 under clause (i) in the Federal Register
25 and as otherwise determined appropriate

1 by the Secretary (including the Internet)
2 to inform the general public. The Secretary
3 shall annually publish (in accordance with
4 the preceding sentence) the status of all
5 States with respect to certifications.

6 (5) STATE CHALLENGE.—A State that has a
7 certification disapproved by the Secretary under
8 paragraph (4) may challenge such disapproval in the
9 appropriate United States district court. The court
10 shall make a de novo determination with respect to
11 a challenge brought under this paragraph.

12 (6) TERMINATION OF CERTIFICATION.—

13 (A) IN GENERAL.—The Secretary, not
14 more frequently than once every 5 years, may
15 request that a State with respect to which a
16 certification has been approved under para-
17 graph (4), submit an assurance to the Secretary
18 that with respect to a certification, the State
19 law involved has not been—

20 (i) repealed; or

21 (ii) modified to such an extent that
22 such law is no longer consistent with a pa-
23 tient protection requirement under this
24 title.

1 (B) TERMINATION.—If a State fails to
2 submit an assurance to the Secretary under
3 subparagraph (A) within the 60-day period be-
4 ginning on the date on which the Secretary
5 makes a request for such an assurance, the cer-
6 tification applicable to the State under this sec-
7 tion shall terminate.

8 (7) RULE OF CONSTRUCTION.—Nothing in this
9 section shall be construed to prohibit a State from
10 submitting more than one certification under para-
11 graph (1).

12 (8) PETITIONS BY PLANS OR ISSUERS.—

13 (A) PETITION PROCESS.—Effective on the
14 date on which the provisions of this Act become
15 effective, as provided for in section 501, a
16 group health plan or health insurance issuer
17 may submit a petition to the Secretary for a de-
18 termination as to whether or not a standard or
19 requirement under a State law applicable to the
20 plan or issuer, that is not the subject of a cer-
21 tification under subsection (c), is superseded
22 under subsection (a)(1) because such standard
23 or requirement prevents the application of a re-
24 quirement of this title.

1 (B) APPROVAL.—The Secretary shall issue
2 a determination with respect to a petition sub-
3 mitted under subparagraph (A) within the 60-
4 day period beginning on the date on which such
5 petition is submitted.

6 (d) PATIENTS' PROTECTION BOARD.—

7 (1) ESTABLISHMENT OF BOARD.—

8 (A) IN GENERAL.—There is hereby estab-
9 lished in the Department of Health and Human
10 Services a Patients' Protection Board. Con-
11 sistent with the requirements of sections 5 and
12 10 of the Federal Advisory Committee Act, the
13 Board shall carry out the duties described in
14 paragraph (2).

15 (B) COMPOSITION.—The Board shall be
16 composed of 13 members appointed by the Sec-
17 retary with balanced representation from
18 among individuals who represent consumers,
19 employers, health professionals, health insur-
20 ance issuers, and officials of State government.
21 Members shall first be appointed to the Board
22 not later than May 1, 2002.

23 (C) TERMS.—The terms of the members of
24 the Board shall be for 3 years except that for
25 the members first appointed the Secretary shall

1 designate staggered terms of 3 years for 2
2 members, 2 years for 2 members, and 1 year
3 for 1 member. A vacancy on the Board shall be
4 filled in the same manner in which the original
5 appointment was made and a member ap-
6 pointed to fill a vacancy occurring before the
7 expiration of the term for which the member's
8 predecessor was appointed shall be appointed
9 only for the remainder of that term.

10 (2) DUTIES.—

11 (A) REVIEW OF CERTIFICATIONS SUB-
12 MITTED.—The Board shall review certifications
13 submitted under subsection (c) and make rec-
14 ommendations to the Secretary of Health and
15 Human Services as provided for in such sub-
16 section.

17 (B) ANNUAL CONGRESSIONAL REPORTS.—

18 (i) IN GENERAL.—The Board shall
19 submit to Congress an annual report on its
20 activities. Each such report shall include
21 the findings of the Board as to—

22 (I) the States that have failed to
23 obtain a certification under subsection
24 (c); and

1 (II) whether the enforcement role
 2 of the Federal Government with re-
 3 spect to health insurance has substan-
 4 tially expanded.

5 (ii) INITIAL REPORT.—The first an-
 6 nual report under clause (i) shall focus
 7 specifically on the development by the
 8 Board of criteria for the evaluation of
 9 State laws and any other activities of the
 10 Board during its first year of operation.

11 (e) DEFINITIONS.—For purposes of this section:

12 (1) BOARD.—The term “Board” means the Pa-
 13 tients’ Protection Board established under sub-
 14 section (d).

15 (2) STATE, STATE LAW.—The terms “State”
 16 and “State law” shall have the meanings given such
 17 terms in section 2723(d) of the Public Health Serv-
 18 ice Act (42 U.S.C. 300gg–23(d)).

19 **Subtitle F—Miscellaneous** 20 **Provisions**

21 **SEC. 161. DEFINITIONS.**

22 (a) INCORPORATION OF GENERAL DEFINITIONS.—
 23 Except as otherwise provided, the provisions of section
 24 2791 of the Public Health Service Act shall apply for pur-

1 poses of this title in the same manner as they apply for
2 purposes of title XXVII of such Act.

3 (b) SECRETARY.—Except as otherwise provided, the
4 term “Secretary” means the Secretary of Health and
5 Human Services, in consultation with the Secretary of
6 Labor.

7 (c) ADDITIONAL DEFINITIONS.—For purposes of this
8 title:

9 (1) ENROLLEE.—The term “enrollee” means,
10 with respect to health insurance coverage offered by
11 a health insurance issuer, an individual enrolled with
12 the issuer to receive such coverage.

13 (2) HEALTH CARE PROFESSIONAL.—The term
14 “health care professional” means an individual who
15 is licensed, accredited, or certified under State law
16 to provide specified health care services and who is
17 operating within the scope of such licensure, accredi-
18 tation, or certification.

19 (3) HEALTH CARE PROVIDER.—The term
20 “health care provider” includes a physician or other
21 health care professional, as well as an institutional
22 or other facility or agency that provides health care
23 services and that is licensed, accredited, or certified
24 to provide health care items and services under ap-
25 plicable State law.

1 (4) NETWORK.—The term “network” means,
2 with respect to a group health plan or health insur-
3 ance issuer offering health insurance coverage, the
4 participating health care professionals and providers
5 through whom the plan or issuer provides health
6 care items and services to participants, beneficiaries,
7 or enrollees.

8 (5) NONPARTICIPATING.—The term “non-
9 participating” means, with respect to a health care
10 provider that provides health care items and services
11 to a participant, beneficiary, or enrollee under group
12 health plan or health insurance coverage, a health
13 care provider that is not a participating health care
14 provider with respect to such items and services.

15 (6) PARTICIPATING.—The term “participating”
16 means, with respect to a health care provider that
17 provides health care items and services to a partici-
18 pant, beneficiary, or enrollee under group health
19 plan or health insurance coverage offered by a
20 health insurance issuer, a health care provider that
21 furnishes such items and services under a contract
22 or other arrangement with the plan or issuer.

23 (7) PRIOR AUTHORIZATION.—The term “prior
24 authorization” means the process of obtaining prior
25 approval from a health insurance issuer or group

1 health plan for the provision or coverage of medical
2 services.

3 (8) TERMS AND CONDITIONS.—The term
4 “terms and conditions” includes, with respect to a
5 group health plan or health insurance coverage, re-
6 quirements imposed under this title with respect to
7 the plan or coverage.

8 **TITLE II—AMENDMENTS TO THE** 9 **PUBLIC HEALTH SERVICE ACT**

10 **SEC. 201. APPLICATION TO CERTAIN HEALTH INSURANCE** 11 **COVERAGE.**

12 (a) IN GENERAL.—Subpart 2 of part A of title
13 XXVII of the Public Health Service Act (42 U.S.C.
14 300gg–4 et seq.) is amended by adding at the end the
15 following:

16 **“SEC. 2707. PATIENT PROTECTION STANDARDS AND AC-** 17 **COUNTABILITY.**

18 “(a) IN GENERAL.—Each health insurance issuer
19 shall comply with the patient protection requirements
20 under title I of the Bipartisan Patients’ Bill of Rights Act
21 of 2001 with respect to non-Federal governmental group
22 health insurance coverage offered by such issuers, and
23 such requirements shall be deemed to be incorporated into
24 this section.

1 “(b) ACCOUNTABILITY.—The provisions of sections
 2 503 through 503B of the Employee Retirement Income
 3 Security Act of 1974 (as in effect as of the day after the
 4 date of enactment of the Bipartisan Patients’ Bill of
 5 Rights Act of 2001) shall apply to non-Federal govern-
 6 mental group health insurance coverage offered by health
 7 insurance issuers with respect to an enrollee in the same
 8 manner as they apply to health insurance coverage offered
 9 by a health insurance issuer for a participant or bene-
 10 ficiary in connection with a group health plan and the re-
 11 quirements referred to in such sections shall be deemed
 12 to be incorporated into this section. For purposes of this
 13 subsection, references in such sections 503 through 503B
 14 to the Secretary shall be deemed to be references to the
 15 Secretary of Health and Human Services.”.

16 (b) CONFORMING AMENDMENT.—Section
 17 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
 18 is amended by inserting “(other than section 2707)” after
 19 “requirements of such subparts”.

20 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
 21 **ANCE COVERAGE.**

22 Part B of title XXVII of the Public Health Service
 23 Act (42 U.S.C. 300gg–41 et seq.) is amended—

24 (1) by redesignating the first subpart 3 (relat-
 25 ing to other requirements) as subpart 2; and

1 (2) by inserting after section 2752 the fol-
2 lowing:

3 **“SEC. 2753. PATIENT PROTECTION STANDARDS AND AC-**
4 **COUNTABILITY.**

5 “(a) IN GENERAL.—Each health insurance issuer
6 shall comply with the patient protection requirements
7 under subtitles A and B of title I of the Bipartisan Pa-
8 tients’ Bill of Rights Act of 2001 with respect to individual
9 health insurance coverage it offers, and such requirements
10 shall be deemed to be incorporated into this section.”.

11 “(b) ACCOUNTABILITY.—The provisions of sections
12 503 through 503B of the Employee Retirement Income
13 Security Act of 1974 (as in effect as of the day after the
14 date of enactment of the Bipartisan Patients’ Bill of
15 Rights Act of 2001) shall apply to health insurance cov-
16 erage offered by a health insurance issuer in the individual
17 market with respect to an enrollee in the same manner
18 as they apply to health insurance coverage offered by a
19 health insurance issuer for a participant or beneficiary in
20 connection with a group health plan and the requirements
21 referred to in such sections shall be deemed to be incor-
22 porated into this section. For purposes of this subsection,
23 references in such sections 503 through 503B to the Sec-
24 retary shall be deemed to be references to the Secretary
25 of Health and Human Services.”.

1 **SEC. 203. LIMITATION ON AUTHORITY OF THE SECRETARY**
 2 **OF HEALTH AND HUMAN SERVICES WITH RE-**
 3 **SPECT TO NON-FEDERAL GOVERNMENTAL**
 4 **PLANS.**

5 Section 2722(b) of the Public Health Service Act (42
 6 U.S.C. 300gg–22(b)) is amended—

7 (1) in paragraph (1), by striking “only—” and
 8 all that follows through the period and inserting
 9 “only as provided under subsection (a)(2).”; and

10 (2) in paragraph (2)—

11 (A) in subparagraph (A), by striking “any
 12 non-Federal governmental plan that is a group
 13 health plan and”; and

14 (B) in subparagraph (B), by striking
 15 “by—” and all that follows through the period
 16 and inserting “by a health insurance issuer, the
 17 issuer is liable for such penalty.”.

18 **SEC. 204. COOPERATION BETWEEN FEDERAL AND STATE**
 19 **AUTHORITIES.**

20 Part C of title XXVII of the Public Health Service
 21 Act (42 U.S.C. 300gg–91 et seq.) is amended by adding
 22 at the end the following:

23 **“SEC. 2793. COOPERATION BETWEEN FEDERAL AND STATE**
 24 **AUTHORITIES.**

25 “(a) AGREEMENT WITH STATES.—A State may enter
 26 into an agreement with the Secretary for the delegation

1 to the State of some or all of the Secretary's authority
 2 under this title to enforce the requirements applicable
 3 under title I of the Bipartisan Patients's Bill of Rights
 4 Act of 2001 to health insurance issuers in connection with
 5 non-Federal governmental plans and individual health in-
 6 surance coverage.

7 “(b) DELEGATIONS.—Any department, agency, or in-
 8 strumentality of a State to which authority is delegated
 9 pursuant to an agreement entered into under this section
 10 may, if authorized under State law and to the extent con-
 11 sistent with such agreement, exercise the powers of the
 12 Secretary under this title which relate to such authority.”.

13 **TITLE III—AMENDMENTS TO**
 14 **THE EMPLOYEE RETIREMENT**
 15 **INCOME SECURITY ACT OF**
 16 **1974**

17 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
 18 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 19 **HEALTH INSURANCE COVERAGE UNDER THE**
 20 **EMPLOYEE RETIREMENT INCOME SECURITY**
 21 **ACT OF 1974.**

22 Subpart B of part 7 of subtitle B of title I of the
 23 Employee Retirement Income Security Act of 1974 (29
 24 U.S.C. 1185 et seq.) is further amended by adding at the
 25 end the following new section:

1 **“SEC. 714. PATIENT PROTECTION STANDARDS.**

2 “(a) IN GENERAL.—Subject to subsection (b), a
3 group health plan (and a health insurance issuer offering
4 health insurance coverage in connection with a group
5 health plan) shall comply with the requirements of title
6 I of the Bipartisan Patients’ Bill of Rights Act of 2001
7 (as in effect as of the date of the enactment of such Act),
8 and such requirements shall be deemed to be incorporated
9 into this subsection.

10 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
11 MENTS.—

12 “(1) SATISFACTION OF CERTAIN REQUIRE-
13 MENTS THROUGH INSURANCE.—For purposes of
14 subsection (a), insofar as a group health plan pro-
15 vides benefits in the form of health insurance cov-
16 erage through a health insurance issuer, the plan
17 shall be treated as meeting the following require-
18 ments of title I of the Bipartisan Patients’ Bill of
19 Rights Act of 2001 with respect to such benefits and
20 not be considered as failing to meet such require-
21 ments because of a failure of the issuer to meet such
22 requirements so long as the plan sponsor or its rep-
23 resentatives did not cause such failure by the issuer:

24 “(A) Section 101 (relating to access to
25 emergency care).

1 “(B) Section 102 (relating to consumer
2 choice option).

3 “(C) Section 103 (relating to patient ac-
4 cess to obstetrical and gynecological care).

5 “(D) Section 104 (relating to access to pe-
6 diatric care).

7 “(E) Section 105 (relating to timely access
8 to specialists).

9 “(F) Section 106 (relating to continuity of
10 care), but only insofar as a replacement issuer
11 assumes the obligation for continuity of care.

12 “(G) Section 108 (relating to access to
13 needed prescription drugs).

14 “(H) Section 109 (relating to coverage for
15 individuals participating in approved clinical
16 trials).

17 “(I) Section 110 (relating to required cov-
18 erage for minimum hospital stay for
19 mastectomies and lymph node dissections for
20 the treatment of breast cancer and coverage for
21 secondary consultations).

22 “(J) Section 121 (relating to the provision
23 of information).

24 “(2) APPLICATION TO PROHIBITIONS.—Pursu-
25 ant to rules of the Secretary, if a health insurance

1 issuer offering health insurance coverage in connec-
2 tion with a group health plan takes an action in vio-
3 lation of any of the following sections of the Bipar-
4 tisan Patients' Bill of Rights Act of 2001, the group
5 health plan shall not be liable for such violation un-
6 less the plan caused such violation:

7 “(A) Section 107 (relating to prohibition of
8 interference with certain medical communica-
9 tions).

10 “(B) Section 111 (relating to prohibition
11 of discrimination against providers based on li-
12 censure).

13 “(3) CONSTRUCTION.—Nothing in this sub-
14 section shall be construed to affect or modify the re-
15 sponsibilities of the fiduciaries of a group health
16 plan under part 4 of subtitle B.

17 “(4) TREATMENT OF CONSISTENT STATE
18 LAWS.—For purposes of applying this subsection, a
19 health insurance issuer offering coverage in connec-
20 tion with a group health plan (and such group
21 health plan) shall be deemed to be in compliance
22 with one or more of the patient protection require-
23 ments of the Bipartisan Patients' Bill of Rights Act
24 of 2001 (as defined in section 151(b)(3) of such

1 Act) that are otherwise applicable to such issuer (or
2 plan) under this section where—

3 “(A) the issuer (or plan) is in compliance
4 with a State law, with respect to the patient
5 protection requirements involved, that has been
6 certified in accordance with section 151(c) of
7 such Act; or

8 “(B) the issuer (or plan) is in compliance
9 with a State law, with respect to the patient
10 protection requirements involved, that has been
11 determined by the Secretary as not preventing
12 the application of the patient protection re-
13 quirements involved, in accordance with section
14 151(c)(8)(B) of such Act.

15 “(c) CONFORMING REGULATIONS.—The Secretary
16 shall issue regulations to coordinate the requirements on
17 group health plans and health insurance issuers under this
18 section with the requirements imposed under the other
19 provisions of this title.”.

20 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE
21 REQUIREMENT.—Section 503 of the Employee Retirement
22 Income Security Act of 1974 (29 U.S.C. 1133) is
23 amended—

24 (1) by inserting “(a)” after “SEC. 503.”; and

25 (2) by adding at the end the following:

1 “(b) In the case of a group health plan (as defined
 2 in section 733) compliance with the requirements of sub-
 3 title A of title I of the Bipartisan Patients’ Bill of Rights
 4 Act of 2001, and compliance with regulations promulgated
 5 by the Secretary, in the case of a claims denial shall be
 6 deemed compliance with subsection (a) with respect to
 7 such claims denial.”.

8 (c) ENFORCEMENT.—Section 502(b)(3) of the Em-
 9 ployee Retirement Income Security Act of 1974 (29
 10 U.S.C. 1132(b)(3)) is amended—

11 (1) by striking “The Secretary” and inserting
 12 “(A) The Secretary”; and

13 (2) by adding at the end the following:

14 “(B) A participant, beneficiary, plan fiduciary, or the
 15 Secretary may not bring an action to enforce the require-
 16 ments of section 714 against a health insurance issuer of-
 17 fering coverage in connection with a group health plan (or
 18 such group health plan) where the patient protection re-
 19 quirements of the Bipartisan Patients’ Bill of Rights Act
 20 of 2001 (as defined in section 151(b)(3) of such Act) oth-
 21 erwise applicable to such issuer (or plan) under section
 22 714 do not apply because the issuer (or plan) is in compli-
 23 ance with a State law, with respect to the patient protec-
 24 tion requirements involved, that has been certified or a

1 determination made in accordance with section 151 of
2 such Act.”.

3 (d) CONFORMING AMENDMENTS.—

4 (1) Section 732(a) of the Employee Retirement
5 Income Security Act of 1974 (29 U.S.C. 1185(a)) is
6 amended by striking “section 711” and inserting
7 “sections 711 and 714”.

8 (2) The table of contents in section 1 of the
9 Employee Retirement Income Security Act of 1974
10 is amended by inserting after the item relating to
11 section 713 the following new item:

“Sec. 714. Patient protection standards.”.

12 (3) Section 502(b)(3) of the Employee Retirement
13 Income Security Act of 1974 (29 U.S.C.
14 1132(b)(3)) is amended by inserting “(other than
15 section 135(b))” after “part 7”.

16 **SEC. 302. COOPERATION BETWEEN FEDERAL AND STATE**
17 **AUTHORITIES.**

18 Section 506 of the Employee Retirement Income Se-
19 curity Act of 1974 (29 U.S.C. 1136) is amended by adding
20 at the end the following:

21 “(c) RESPONSIBILITY OF STATE WITH RESPECT TO
22 HEALTH INSURANCE ISSUERS.—

23 “(1) AGREEMENT WITH STATES.—A State may
24 enter into an agreement with the Secretary for the
25 delegation to the State of some or all of the Sec-

retary's authority under sections 502, 503A, 503B,
or 504 to enforce the requirements applicable under
title I of the Bipartisan Patients's Bill of Rights Act
of 2001 to health insurance issuers in connection
with a group health plan.

“(2) DELEGATIONS.—Any department, agency,
or instrumentality of a State to which authority is
delegated pursuant to an agreement entered into
under this subsection may, if authorized under State
law and to the extent consistent with such agree-
ment, exercise the powers of the Secretary under
this title which relate to such authority.”.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

SEC. 401. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue
Code of 1986 is amended—

(1) in the table of sections, by inserting after
the item relating to section 9812 the following new
item:

“Sec. 9813. Standard relating to patients' bill of rights.”;

and

(2) by inserting after section 9812 the fol-
lowing:

1 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**
 2 **RIGHTS.**

3 “A group health plan shall comply with the require-
 4 ments of title I of the Bipartisan Patients’ Bill of Rights
 5 Act of 2001 (as in effect as of the date of the enactment
 6 of such Act), and such requirements shall be deemed to
 7 be incorporated into this section.”.

8 **SEC. 402. CONFORMING ENFORCEMENT FOR WOMEN’S**
 9 **HEALTH AND CANCER RIGHTS.**

10 Subchapter B of chapter 100 of the Internal Revenue
 11 Code of 1986, as amended by section 401, is further
 12 amended—

13 (1) in the table of sections, by inserting after
 14 the item relating to section 9813 the following new
 15 item:

“Sec. 9814. Standard relating to women’s health and cancer
 rights.”;

16 and

17 (2) by inserting after section 9813 the fol-
 18 lowing:

19 **“SEC. 9814. STANDARD RELATING TO WOMEN’S HEALTH**
 20 **AND CANCER RIGHTS.**

21 “The provisions of section 713 of the Employee Re-
 22 tirement Income Security Act of 1974 (as in effect as of
 23 the date of the enactment of this section) shall apply to
 24 group health plans as if included in this subchapter.”.

1 **TITLE V—EFFECTIVE DATE;**
 2 **SEVERABILITY**

3 **SEC. 501. EFFECTIVE DATE AND RELATED RULES.**

4 Except as otherwise provided in this Act, the provi-
 5 sions of this Act, including the amendments made by title
 6 I, shall apply on the later of—

7 (1) plan years beginning on or after January 1,
 8 2003; or

9 (2) plan years beginning on or after 18 months
 10 after the date on which the Secretary of Health and
 11 Human Services and the Secretary of Labor issue
 12 final regulations, subject to the notice and comment
 13 period required under subchapter 2 of chapter 5 of
 14 title 5, United States Code, necessary to carry out
 15 the amendments made by this Act.

16 **SEC. 502. SEVERABILITY.**

17 (a) IN GENERAL.—Except as provided in subsections
 18 (b) and (c), if any provision of this Act, an amendment
 19 made by this Act, or the application of such provision or
 20 amendment to any person or circumstance is held to be
 21 unconstitutional, the remainder of this Act, the amend-
 22 ments made by this Act, and the application of the provi-
 23 sions of such to any person or circumstance shall not be
 24 affected thereby.

1 (b) DEPENDENCE OF REMEDIES ON APPEALS.—If
2 any provision of section 131, or the amendments made by
3 such section, or the application of such section or amend-
4 ments to any person or circumstance is held to be uncon-
5 stitutional, sections 141 and 143, and the amendments
6 made by such sections, shall be deemed to be null and
7 void and shall be given no force or effect.

8 (c) REMEDIES.—If any provision of section 141, or
9 the amendments made by such section, or the application
10 of such section or amendments to any person or cir-
11 cumstance is held to be unconstitutional, the remainder
12 of such section, and the amendments made by such section
13 shall be deemed to be null and void and shall be given
14 no force or effect.

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